UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 17-op-45004

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.
Case No. 18-op-45090

MDL No. 2804

Hon. Dan Aaron Polster

EXPERT REPORT OF JOHN J. MACDONALD III

May 10, 2019

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I. EXECUTIVE SUMMARY

1. I, John J. MacDonald III, hereby submit this report of my opinions in the above-captioned matter.

2. The opinions in this report are my own and are based upon my education, professional experience, and examination of the documents, electronic data, and other information provided by the parties in this action. I am independent from all parties and their legal advisors and affirm my genuine belief in the opinions expressed in this report. A detailed recitation of my opinions and work performed is discussed throughout the remainder of this report.

3. I understand that the above-captioned lawsuit, Track One of In Re National Prescription Opiate Litigation is a litigation brought by Cuyahoga County and Summit County (collectively referred to as "Plaintiffs" or "Track 1 Counties"), alleges among other things that the defendant manufacturers' conduct in promoting opioid use has allegedly led to improper opioid use causing the Plaintiffs to incur increased costs in public health, social services, criminal justice consequences, and increased need for services. The Plaintiffs have also alleged that the parties in the supply chain for opioids, which includes manufacturers, distributors, and pharmacies, have failed to maintain effective controls over the distribution of prescription opioids.[1]

4. Cardinal Health, Inc. ("Cardinal") is a pharmaceutical distributor contracted to provide prescription drugs from hundreds of manufacturers to thousands of government-authorized pharmacies that fill doctors' prescriptions for patients. As will be discussed in more detail below, Cardinal facilitates the chain of distribution of pharmaceuticals. Cardinal does not manufacture, promote, or prescribe medications to members of the public.[2]

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[1] In Re National Prescription Opiate Litigation, The County of Cuyahoga, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 17-OP-45004, Second Amended Complaint, May 30, 2018, ("Cuyahoga Complaint"), ¶ 14; In Re National Prescription Opiate Litigation, The County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 17-md-2804, Amended Complaint and Jury Demand, April 25, 2018, ("Summit Complaint"), ¶ 14.

[2] Cardinal Health Fiscal 2018 Form 10-K, p. 3 found at https://www.sec.gov/Archives/edgar/data/721371/000072137118000077/a18q4_10kx063018xform10-k.htm, last accessed May 8, 2019.

5. Counsel for Defendant Cardinal has requested that I review and opine on the report of Plaintiffs' expert Craig J. McCann, Ph.D., CFA ("McCann Report") by reviewing the methods prepared by McCann and assessing their accuracy and reasonableness for retrospectively assessing purchasing patterns of individual Cardinal customers.[3] Although not my primary assignment, I have also been asked to address certain items contained in the reports of James E. Rafalski ("Rafalski"), David Cutler, Ph.D. ("Cutler"), Dr. Seth Whitelaw ("Whitelaw"), and Thomas McGuire ("McGuire") which relate to my primary assignment.[4]

6. The authors of the reports named in the preceding paragraph have not all been deposed as of this writing. McCann's deposition was scheduled to continue through today's date, and Rafalski and Whitelaw are scheduled to be deposed later. It is my intention to review and evaluate those deposition transcripts and amend or supplement this report, as appropriate.

7. The Plaintiffs have alleged that Cardinal deliberately disregarded its duty to maintain effective controls and to identify, report, and take steps to halt suspicious orders that were distributed to retail pharmacies. I understand that Cardinal has denied these allegations and maintains that it had adequate systems in place to monitor orders it distributed to retail pharmacies for fulfillment with the reasonable expectation that the drug substance would be dispensed by the retail pharmacies in response to lawful prescriptions.

8. My opinions are presented in greater detail throughout the remainder of this report. In summary, it is my opinion that:

- McCann's purported methods do not identify orders of controlled substances that are of unusual size, pattern, or frequency as required by 21 C.F.R. § 1301.74(b).

[3] Expert Report of Craig J. McCann, Ph.D., CFA, dated March 25, 2019; Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, dated April 3, 2019.

[4] Expert Report of James E. Rafalski, Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances, dated April 15, 2019 ("Rafalski"); Expert Report of Professor David Cutler, dated March 25, 2019; Expert Report of Dr. Seth Whitelaw, Examination of Compliance Standards for Opioid Manufacturers and Distributors, dated April 15, 2019.

- McCann fails to take into account the distributor's role in the supply chain, including but not limited to, fulfillment of medical demand for opioids by pharmacies based on prescriptions from doctors to meet legitimate patient medical needs.

- McCann's methods result in the identification of over [redacted] shipments as "suspicious," a result that does not hold up under further scrutiny. My analysis indicates that over 99% of the shipments identified by McCann are affected by one or more contextual factors that should be taken into account before declaring that an order is of unusual size.

II. QUALIFICATIONS AND COMPENSATION

9. I am President of Berkeley Research Group ("BRG") and a senior member of the BRG Health Analytics practice. I have over 30 years of experience providing economic, financial, accounting, and data management consulting services to clients in the healthcare, financial services, and government contracting industries.

10. I have spent the majority of my professional career focused on data analytics, economic and financial modeling, evaluation of business practice, and regulatory compliance on matters involving a wide array of issues, often related to litigation or investigation driven events and with a particular focus in the healthcare industry. A significant amount of my work has been related to allegations of fraud or other aberrant activities and has required analysis of very large health datasets.

11. Much of my data analytics work has involved detailed analyses of temporal trends and patterns and has often involved developing approaches to identify "outlier" events or activities. Outlier identification typically involves a two-step process: 1) developing programmatic methods to initially flag unusual or unexpected data points from within a much larger population of usual or expected data points; and 2) performing contextual analysis on the flagged items to determine whether unique circumstances exist explaining the unusual or unexpected nature of the flagged items. This contextual analysis is informed by many years of working with a vast array of healthcare related datasets, including provider billing data, electronic medical records data, managed care claim adjudication data, pharmaceutical sales and chargeback data, and pharmacy data. I have a broad working knowledge of the various coding sets used within health data, including procedure related codes (CPT, DRG, APG), diagnostic codes (ICD9/10), drug codes (NDC) and others.

12. I have worked extensively with companies in the pharmaceutical supply chain such as manufacturers, distributors, pharmacy providers, and pharmacy benefit managers on a variety of projects including matters related to pricing, compliance, fraud and abuse issues, coordination of benefits, billings, and collections. I have extensive experience analyzing the contractual relationships and transactions that take place between parties in the pharmaceutical supply chain, including analyzing sales data, purchase data, inventory and ordering data, among other data sets. I have also reviewed policies and procedures and

business practices of numerous providers and payers. I have examined purchase and sales transactions as well as the related accounting records, contracts, and other documents related to the relationships between parties providing healthcare goods and services and the payers for those services. In doing so I have developed expertise in the flow of money and goods in the healthcare system, including within the pharmaceutical supply chain, as well as the transactional data that record those interactions.

13. My Curriculum Vitae, which describes in detail my professional and testifying experience, as well as my educational credentials, is attached as Attachment 1.

14. BRG bills for professional services rendered based on actual hours incurred at contractually agreed upon rates per hour. My hourly billing rate is $725.

15. BRG's compensation in this matter is not dependent on, or in any way contingent upon, my findings or opinions.

16. See Attachment 2 for a list of materials I considered in preparing this report.

III. BACKGROUND

A. Brief Overview of McCann's Report

17. The McCann Report includes the results of 5 different methods he uses to analyze the shipment of opioid products based on the Automated Records and Consolidated Orders System ("ARCOS")[5] data (as augmented by certain transaction data produced by defendants deemed to be missing from the ARCOS data) for 12 controlled substance drug codes by Cardinal to pharmacy customers in Cuyahoga and Summit counties ("McCann Dataset").[6,7] At a high level, each of McCann's methods uses a different formulaic method to identify (or "flag") shipments that meet predetermined criteria. I understand that the analysis presented in the McCann Report has been used to suggest that the flagged shipments should have been reported to the United States Drug Enforcement Agency ("DEA") for further investigation as part of Cardinal's responsibilities as a distributor to "design and operate a system" to identify "suspicious orders of controlled substances."[8] McCann does not comment or opine on the sufficiency of any system used by Cardinal to flag or investigate shipments, but he assumes that Cardinal has not effectively investigated any flagged transaction.[9]

18. I am not aware that any method described in the McCann Report has been formally endorsed by statute, the DEA, the Food and Drug Administration ("FDA"), or any other regulatory body as an acceptable methodology to identify suspicious orders of controlled substances that require disclosure to DEA in order to meet the statutory obligations of 21

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5 "ARCOS" refers to the automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the retail level. The system was developed by DEA and is maintained by the Department of Justice Data Center and the DEA Data Center.

6 In addition to describing his various methods for flagging shipments, the McCann Report also includes a description of how he validated and corrected transaction data produced in this case, namely transaction data produced by the DEA (DEA Retail Drug Summary Reports and ARCOS data) and by defendants. I have not independently verified that these datasets are complete and reliable; however, for the purpose of my analysis presented herein, I do not dispute the use of these datasets.

7 McCann excludes transactions involving two treatment drugs: buprenorphine and methadone.

8 21 C.F.R. § 1301.74(b) ("The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.").

9 McCann Report, ¶¶ 132, 136, 140, 144, 148.

C.F.R. § 1301.74(b). Indeed, the DEA has stated that "DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 821(b)(1)."[10]

19. Deposition testimony given by DEA witnesses in this matter, as well as sworn testimony from DEA personnel in other proceedings, shows that (1) neither the Controlled Substances Act ("CSA") nor its implementing regulations establish a methodology for identifying suspicious orders; (2) DEA personnel responsible for creating and implementing DEA's policies relative to suspicious orders specifically refused, when asked, to specify a methodology that wholesale distributors and other registrants should use to identify suspicious orders; and (3) that the basis for that refusal was the belief within DEA that wholesale distributors and other registrants had a responsibility to define their own metrics for identifying suspicious orders based upon their knowledge of the legitimate needs of their customers.[11]

20. I understand from the reports of Plaintiffs' experts Rafalski, Cutler, and McGuire that it is suggested Cardinal should have or could have used one or more of McCann's methodologies to flag suspicious orders. For the reasons stated in this report, I disagree that any of these retrospective analyses properly identifies suspicious orders of controlled substances or would be useful to identify suspicious orders in Cardinal's system. Rafalski, McGuire, and Cutler identify no evidence that any one or more of McCann's methods that they endorse or rely upon was required instead of the methodologies Cardinal actually employed. DEA personnel have indicated that no one method in particular was (or is) required, much less that any of McCann's methods in particular were required. The methodologies endorsed and relied upon by Plaintiffs' experts are deficient in that they do not account for customer-specific factors that the DEA has suggested Cardinal and other registrants take into account, and because they result in the identification of hundreds of thousands of shipments as "suspicious" they do not hold up under further scrutiny.

[10] McKesson Settlement Memorandum of Agreement, dated January 17, 2017.
[11] Congressional Statement of Joseph Rannazzisi 3-1-2012, p. 93-4.

B. Opioids and the Controlled Substances Act

21. The CSA, which was enacted in 1970, identified drugs that were determined to have a useful and legitimate medical purpose but that concern of illegal importation, manufacture, distribution, and improper use have the potential for a detrimental effect on the heath and general welfare of the population.[12] The CSA established federal control of the traffic of the drugs included in the identified list of substances.

22. Five drug schedules were established as part of the CSA, and part of the regulation required that any provider that prescribed or pharmacist that filled any of these substances must obtain a license from the DEA to allow tracking of controlled substance prescriptions to a particular provider or distributor.

23. The schedules of product range from Schedule I (most potential for addiction or use disorder) to Schedule V (least potential for addiction or use disorder), and DEA, in conjunction with recommendations by U.S. Department of Health and Human Services (HHS), makes the final determination for how a product should be controlled.[13] McCann's report focuses on 12 different opioid[14] drug products that are all identified as Schedule II[15] products for at least part of the time period he analyzed.

24. The amount of Schedule I[16] and II products that can be manufactured per year is governed by the Aggregate Production Quota (APQ) that is set annually by the DEA.[17] The APQ reflects the annual quantities "to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the

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12 21 U.S.C. § 801.
13 21 U.S.C. § 811(b), 812.
14 U.S. Department of Health and Human Services defines opioids as a "class of drugs that include the illegal drug heroin, synthetic opioids such as fentanyl, and pain relievers available legally by prescription, such as oxycodone (OxyContin®), hydrocodone (Vicodin®), codeine, morphine, and many others.", found at https://www.hhs.gov/opioids/prevention/index.html, last accessed 5/9/2019.
15 21 U.S.C. § 812(b). Schedule II are products that have a high potential for abuse which may lead to severe psychological or physical dependence.
16 21 U.S.C. § 812(b). Schedule I products are those that have no currently accepted medical use and a high potential for abuse. Some examples of Schedule I products include heroin, ecstasy, and peyote.
17 21 U.S.C. § 826 requires the Attorney General to set APQs for products listed in Schedules I and II. The Attorney General delegated this function to the DEA under 28 C.F.R. § 0.100.

establishment and maintenance of reserve stocks."[18] The DEA assigns individual production quotas to controlled substance manufacturers in order to prevent the APQ from being exceeded.[19] A manufacturer may not manufacture a Schedule I or II product that is not expressly authorized by its registration and by the individual quota assigned to it by the DEA, or in excess of that quota.[20] I analyze the historical APQ amounts within this report.

1. Rescheduling of Hydrocodone Combination Products

25. One of the substances included in McCann's Report is hydrocodone, which includes products such as Vicodin® (hydrocodone in combination with acetaminophen). In 2009, DEA requested a recommendation from HHS concerning whether to reschedule all hydrocodone combination products from Schedule III to Schedule II.[21] Conforming to HHS's recommendation, in 2014, DEA published a final rule that administratively rescheduled hydrocodone combination products from Schedule III to Schedule II.

2. Special Storage and Prescription Requirements for Schedule II Products

26. I understand that requirements exist for prescriptions related to Schedule II products that differ from other scheduled and non-scheduled products. The following is not an exhaustive list of specialized regulations for Schedule II products; however, these differences are relevant to later sections of my report.

27. I understand that distributors are required to store Schedule II-V products in electronically monitored safes, steel cabinets, or vaults that meet or exceed certain specifications.[22] Pharmacies must store controlled substances in a "securely locked, substantially constructed cabinet" and must notify the DEA of the theft or significant loss of any

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[18] 21 U.S.C. § 826(a)(1). Schedule I products may only be used for research, as they have no accepted medical purpose in the United States.
[19] 21 U.S.C. § 826(b).
[20] 21 U.S.C. § 842(b).
[21] Drug Enforcement Administration, Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 79 Fed. Reg. 49,661, 49,662 (Aug. 22, 2014).
[22] 21 C.F.R. § 1301.72.

controlled substances.[23] Schedule II-V products may alternatively be stored among other prescription drugs.[24]

28. I understand that DEA has certain additional requirements for dispensing of a Schedule II product in comparison to Schedule III – IV and non-scheduled prescription products.[25] Schedule II products may not be dispensed to a patient by a pharmacist without a written prescription from a practitioner (except in cases where the practitioner directly administers the controlled substance to the patient or emergency situations).[26] Schedule III-V products may be dispensed by a pharmacy pursuant to either a written or oral prescription, including a facsimile of a written prescription, or by electronic prescription assuming that the electronic prescription complies with the detailed requirements set forth in the applicable federal regulations.[27]

29. All controlled substance prescriptions must be dated as of the date of issuance; in other words, a prescriber may not predate or postdate prescriptions. In addition to the date of issuance, all controlled substance prescriptions must contain at least the following information: the full name and address of the patient; the name, address, and registration number of the practitioner; the drug name, strength, and dosage form; the quantity prescribed, and directions for use.[28] Before filling the prescription in the pharmacy, regulations also require the prescription to contain the written or typewritten name or initials of the pharmacist dispensing the drug, the date dispensed, and the number of units or volume dispensed.[29]

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[23] 21 C.F.R. § 1301.75(b).
[24] 21 C.F.R. § 1301.75(b).
[25] I understand that certain states may have requirements in addition to DEA requirements for the dispensing of Schedule II products. However, Plaintiffs' proposed experts have not identified any material differences between those requirements and the ones imposed under the CSA and associated regulations. For the purposes of this report, I refer only to the federal requirements and their interpretation by DEA.
[26] 21 U.S.C. § 829(a); 21 C.F.R. § 1306.05, 1306.11(b). The DEA has provided for a few special exceptions that allow for an electronic prescription for a Schedule II product. See, for example, 21 C.F.R. § 1306.11(e) (permitting a faxed Schedule II product prescription if the Scheduled II product is to be compounded for the direct administration to a patient, such as by parenteral or intravenous infusion).
[27] 21 U.S.C. § 829(b); Drug Enforcement Administration, Electronic Prescriptions for Controlled Substances, 75 Fed. Reg. 16235, 16316 (Mar. 31, 2010).
[28] 21 C.F.R. § 1306.05(a).
[29] 21 C.F.R. § 1304.22(c).

30. I also understand that there is a difference in the inventory requirements for Schedule II and Schedule III-V products. It is required that there is a complete and accurate record of all controlled substances on hand and that such inventory must be determined by an actual physical count for Schedule II products and an estimated count or measure of the contents of a Schedule III, IV, or V products (unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made).[30] The inventory records of Schedule II products must be kept separate from all other controlled substances. Additionally, I understand from my experience in this industry that many pharmacies, either by state regulation or store policy, require that there is a perpetual inventory with a monthly reconciliation of all Schedule II products.[31]

C. Role of Distributors

31. In general, the supply chain for controlled substances starts with the manufacturer, and products often move from a manufacturer to pharmacies with the help of distributors such as Cardinal. Pharmacies may order from multiple distributors. The usual movement of a controlled substance from a manufacturer to a patient has been described as:

> [A] controlled substance, after being manufactured by a DEA-registered manufacturer, may be transferred to a DEA-registered distributor for subsequent distribution to a DEA-registered retail pharmacy. After a DEA-registered practitioner, such as a physician or a dentist, issues a prescription for a controlled substance to a patient (i.e., the ultimate user), that patient can fill that prescription at a retail pharmacy to obtain that controlled substance. In this system, the manufacturer, the distributor, the practitioner, and the retail pharmacy are all required to be DEA registrants, or to be exempted from the requirement of registration, to participate in the process.[32]

32. The following graphic illustrates the movement of a controlled substance as described above. I understand that all parties along the product flow (other than the patient) are DEA registrants and have a responsibility to maintain effective controls against diversion. Further, the interactions between the pharmacy, patient, and doctor are the only points within the product flow where there is an exchange of patient-specific clinical data

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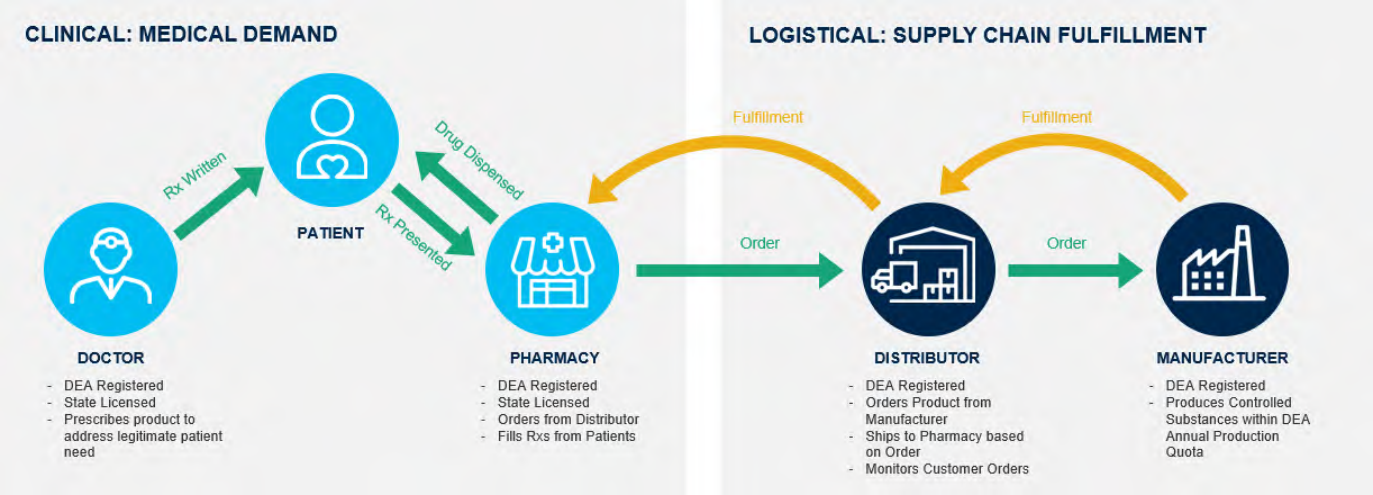
30 21 C.F.R. § 1304.11(e)(3).

31 FDA Recommends Reclassifying Hydrocodone to Schedule II, found at https://www.pharmacytoday.org/article/S1042-0991(15)31070-7/pdf, p73, last accessed May 9, 2019.

32 DEA, Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration, 74 Fed. Reg. 3480, 3481 (January 21, 2009).

regarding the use of the controlled substance. That clinical interaction culminates in a prescription being presented by the patient at the pharmacy, which the pharmacist would fill absent a suspicion that the prescription is going to be diverted into an illicit channel or is fraudulent. In this way, the clinical events starting with the doctor / patient interaction and a prescription that is written drives the supply chain requirements in terms of shipments by the distributor to the pharmacy.[33]

Figure 1: Example Product Flow for Controlled Substances through Distributor and Retail Pharmacy Channel



33. The DEA has acknowledged that physician prescriptions for controlled substances are generally not fraudulent, stating, "DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes" and "only a tiny fraction of physicians (less than one in ten thousand) lost their registration based on a DEA investigation of improper prescribing of controlled substances."[34]

[33] Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, p4. Available at https://avalere.com/research/docs/Follow_the_Pill.pdf. (Accessed 5/9/2019)

[34] 2006 DEA Notice re Dispensing Controlled Substances for the Treatment of Pain, https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm, Federal Register: September 6, 2006 (Volume 71, Number 172)] [Notices] [Page 52715-52723].

34. All DEA-registered manufacturers and distributors are required to: "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[35]

35. A distributor of Schedule II products may maintain controlled substance registration unless the Attorney General (whose authority is delegated to DEA) determines that the issuance of such registration is inconsistent with the public interest. The following factors shall be considered to determine public interest:[36]

a) Maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

b) Compliance with applicable state and local law;

c) Prior conviction record of applicant under federal or state laws relating to the manufacture, distribution, or dispensing of such substances;

d) Past experience in the distribution of controlled substances; and

e) Such other factors as may be relevant to and consistent with the public health and safety.

36. The DEA has explained that the term "diversion," used in the context of the CSA, refers to "the redirection of controlled substances which may have lawful uses into illicit channels."[37]

[35] 21 C.F.R. § 1301.74.
[36] 21 C.F.R. § 823(b).
[37] Drug Enforcement Administration, Controlled Substances Quotas, 83 Fed. Reg. 32,784 (July 16, 2018).

D. Role of Pharmacy

37. Only a pharmacist who is acting in the usual course of professional practice and who either is registered individually or is employed by a registered pharmacy or other registered entity may fill a prescription for a controlled substance.[38] A pharmacist is defined as a person licensed by a state to dispense controlled substances as well as any other person (e.g., pharmacist intern) authorized to dispense controlled substances under the supervision of a pharmacist.[39]

38. A pharmacy in the practice of dispensing Schedule II-V products[40] must register with the DEA as a dispenser using DEA Form 224. This is a different DEA form than the form required for manufacturers and distributors to register with the DEA.[41]

39. The purpose of a controlled substance prescription is described in the federal regulations as:

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorize research is not a prescription within the meaning and intent of Section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.[42]

40. To help pharmacists ensure that controlled substance prescriptions are being issued for a legitimate medical purpose, the DEA published a guide, *A Pharmacist's Guide to Prescription Fraud*.[43]

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38 21 C.F.R. § 1306.06.
39 Pharmacist's Manual Appendix B, found at https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/appendix/appdx_b.htm, last accessed 5/9/2019.
40 21 C.F.R. § 1301.13(e).
41 Manufacturers and distributors register with the DEA by completing DEA Form 225.
42 21 C.F.R. § 1306.04(a).
43 A Pharmacist's Guide to Prescription Fraud, Appendix D to The Pharmacist's Manual: An Informational Outline of the Controlled Substances Act (revised 2010), found at https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf, last accessed May 4, 2019.

E. Factors Influencing the Volume of Prescriptions Filled by a Pharmacy

41. The volume of prescriptions, including the volume of controlled substances, filled by a pharmacy varies widely from pharmacy to pharmacy. A 2012 Drug Store News survey found that 94% of customers choose their primary pharmacy based on location and convenience.[44] Other factors such as customer service, speed of filling prescriptions, cost, and hours of operation will impact pharmacy choice and the customer demand for a particular pharmacy.[45]

42. It is well recognized that pharmacies with a hospital or relevant clinic affiliation may have an increased volume of controlled substance prescriptions when compared to other similarly situated pharmacies.[46] This is largely due to the patient population that the hospital and clinics are serving, a population that includes trauma patients or patients who have recently undergone surgery.

43. Other recognized factors affecting the volume of controlled substances dispensed by a pharmacy are: type(s) of patient population served; variation in geographical or regional prescribing patterns that may affect which products are prescribed; and, any specialty practice within the pharmacy.[47]

44. It is well recognized that opioid prescribing trends have changed over the past two decades. The medical community shifted patient assessment and treatment to counteract what was viewed as an inadequate focus on pain assessment and treatment. Pain became recognized as the fifth vital sign and "the evolution of patient satisfaction surveys that include a focus on the extent to which a patient's pain is relieved, created a practice environment that, although intended to promote pain assessment and effective treatment, in general ultimately led to an increase in opioid prescriptions." [48] Organizations like the Federation

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44 Drug Store News, How consumers choose a primary pharmacy, found at https://www.drugstorenews.com/pharmacy/how-consumers-choose-primary-pharmacy/, last accessed on May 8, 2019.

45 Ibid.

46 Consensus Document, Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, found at https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf, last accessed May 8, 2019.

47 Ibid.

48 Ibid.

of State Medical Boards encouraged state medical boards to adopt policies that would ensure patients received adequate pain relief and maintain patient access to appropriate pain management, including opioids for the treatment of chronic pain.[49] This prescribing trend was fueled by competing interests such as: under treatment of cancer pain, treating chronic non-cancer pain, the introduction of several new opioid products, and inadequate non-pharmacologic approaches for treatment of pain. These market factors contributed to the "routine use of opioid analgesics." [50]

F. Overview of Suspicious Order Monitoring Systems and Anti-Diversion Program ("ADP")

45. As discussed above, 21 C.F.R. § 1301.74(b) requires that a registrant design and operate a system "to disclose to the registrant suspicious orders of controlled substances" and suspicious orders include orders of unusual size, pattern, or frequency. Additionally, 21 C.F.R. § 1301.71(a) also requires that there are effective controls and procedures to guard against theft and diversion of controlled substances.

46. The only due diligence requirement set forth in the DEA's regulations is found in 21 C.F.R. § 1301.74(a) and requires that:

> Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

47. DEA has been criticized for failing to provide guidance on the suspicious order monitoring regulation, 21 C.F.R. § 1301.74(b).

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[49] Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain, Federation of State Medical Boards (https://www.umhealthpartners.com/wp-content/uploads/2016/10/ChronicPainManagement.pdf, accessed May 9, 2019).

[50] Ibid.

48. Over the years, DEA has primarily set forth its view of the regulation in presentations at conferences, through Memoranda of Agreement ("MOA") related to enforcement actions and in litigation positions such as the DEA's position in the 2017 Masters case.[51]

49. As recently as 2018, the need for DEA to clarify the regulations has been expressed. The 2018 Unified Agenda[52] states: "The Drug Enforcement Administration is proposing to revise its regulations relating to suspicious orders of controlled substances. The proposed rule defines the term suspicious order and specifies the procedures a registrant must follow upon receiving such orders."[53]

[51] Masters Pharmaceuticals, Inc. Decision and Order, 80 Fed. Reg. 55477 (September 15, 2015).
[52] The Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda), publishes in the fall and spring, and describes regulatory actions as they are developing.
[53] Suspicious Orders of Controlled Substances Fall 2018 RIN: 1117-AB47.

IV. SUMMARY OF MCCANN'S ANALYSIS

50. Each of McCann's methods fails to identify suspicious orders of controlled substances. Distributors licensed under the DEA as part of the chain of distribution of controlled substances are required to design and operate a system that would identify suspicious orders of controlled substances such that they can be reported to the DEA. The Code of Federal Regulations ("C.F.R.") defines suspicious orders as being orders of (1) unusual size; (2) orders that deviate from a normal pattern, or (3) orders of unusual frequency.[54] McCann's methods are not well-conceived to flag orders fitting any of those criteria.

51. While the regulations require identification of suspicious orders, they do not prescribe a specific approach for identifying these orders. Thus, there is no objectively verifiable definition of what constitutes an "unusual" order in terms of size, pattern, or frequency. Likewise, testimony and other evidence shows that the DEA has not provided commentary to distributors on the metrics they should use to identify suspicious orders, believing that it was necessary for distributors to define those metrics for themselves.[55] Nevertheless, and despite not providing such up front guidance to distributors, Plaintiff's expert Rafalski's report points to an administrative proceeding in which the DEA took the position that a registrant (in this case, a manufacturer) might evaluate its customers based on, among other things, the "percentage of control substances ordered when compared to non-controlled substances."[56] In that proceeding, the DEA asserted that a ratio of up to 20% controlled substances was consistent with what a "typical retail pharmacy" would order. Although I do not endorse any of Rafalski's opinions on this subject, this 20% figure provides a measure against which McCann's analysis can be evaluated, i.e., by allowing us to see the extent to which his methods result in classifying as "unusual" the orders of pharmacies that are in fact "typical" according to a measure that the DEA and Plaintiffs' proposed DEA expert (Rafalski) have endorsed.[57]

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[54] 21 C.F.R. § 1301.74.

[55] Deposition of Rannazzisi, 4/26/2019, 42:17-46:7; 2015 GAO Report titled "Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access", p. 26-27, 45.

[56] Rafalski, p.19, citing Southwood Pharm., Inc., 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007).

[57] To be clear, variance from that figure would not, in my opinion, constitute an adequate basis to make an affirmative determination that a particular order *is suspicious*, or a basis on which a suspicious order monitoring

52. McCann to systematically applies five different methods and related assumptions to flag shipments of the 12 opioids[58] that meet criteria he defined as a methodology to identify "transactions that warrant some further due diligence."[59] Plaintiffs' expert Rafalski indicates that at least one of McCann's methods (his six-month trailing method, described further below) meets the portion of the DEA definition of a suspicious order in that it "provides…an initial trigger and first step to identify orders of unusual size."[60] I will refer generally to the orders identified by McCann as suspicious orders / orders of unusual size as orders that McCann has "flagged."

53. Each of McCann's five methodologies is described below along with the percentage of total Cardinal dosage units, orders and customers he flags for the years 2006-2017.

system could be designed. My purpose in using that figure here is solely as a reference point against which to assess the adequacy of the various methodologies put forward by McCann.

58 The opioids included are: hydrocodone, oxycodone, morphine, codeine, hydromorphone, fentanyl, oxymorphone, tapentadol, meperidine, dihydrocodeine, levorphanol, opium (powdered).

59 It does not appear that McCann provides an opinion on how any one or more of these methods could or should have been used by Cardinal to identify suspicious orders. However, other Plaintiffs' experts in this matter refer to his six-month trailing method as the model they rely upon to identify suspicious orders of opioids. See, for example, Rafalski, p. 11; Cutler, Appendix III.J; McGuire, p. 9-11. While my report provides an analysis of all 5 methodologies included in McCann's report, I provide a more detailed review of the six-month trailing method due to the weight it has been given by other experts. To the extent McCann or other experts later identify or elaborate on a different methodology, I reserve the right to provide additional information and analysis regarding the identified methodology.

60 Rafalski, p. 46.

Table 1: McCann Methodologies and Percentage Flagged for Cardinal[61]

McCann Method	McCann Method Description	% Dosage Units Flagged	% Orders Flagged	% Customers Flagged
Maximum Monthly, Trailing Six-month Threshold **("six-month trailing")**	Transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months. Every subsequent transaction of that drug code is also flagged.	[redacted]	[redacted]	[redacted]
Twice Trailing Twelve-Month Average Pharmacy Dosage Units **("two times trailing twelve-month")**	Transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor. Every subsequent transaction of that drug code is also flagged.	[redacted]	[redacted]	[redacted]
Three Times Trailing Twelve-Month Average Pharmacy Dosage Units **("three times trailing twelve-month")**	Transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor. Every subsequent transaction of that drug code is also flagged.	[redacted]	[redacted]	[redacted]
Maximum 8,000 Dosage Units Monthly **("8,000 monthly maximum")**	Transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units. Every subsequent transaction of that drug code is also flagged.	[redacted]	[redacted]	[redacted]
Maximum Daily Dosage Units **("maximum daily dosage units")**	Transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation. Every subsequent transaction of that drug code is also flagged.	[redacted]	[redacted]	[redacted]

[61] McCann Report, ¶¶ 131, 136, 140, 144, 148; McCann Dataset.

54. McCann applies each of the methods above to a dataset he created (McCann Dataset) that combines data produced by the DEA and Cardinal (and other distributor) distribution data.[62] When a transaction meets the criteria set by McCann, the shipment is flagged. After a shipment has been flagged, McCann assumes (without basis) that Cardinal performed no due diligence prior to (or after) the shipment and uses that as a rationale to flag all *subsequent* shipments of the same product to that customer.[63] McCann states that he made this assumption at the direction of counsel.[64] As discussed below, this assumption accounts for a majority of the orders McCann flags in his report.

55. As a threshold matter, McCann identifies no basis for the assertion that these specific methods, to the exclusion of other methods, were required of Cardinal to identify suspicious orders. He merely assumes that these are necessary or proper methods. That assumption in turn is the driving force behind his further explicit assumption, made at the direction of counsel, that for any order "flagged" through one of his methods, "the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled *obligation* to detect and investigate the first flagged transaction."[65] McCann's analysis is circular and lacks a solid analytical foundational in several critical ways.

56. First, McCann does not provide a basis for the assumption that if a particular "flagged" shipment was not investigated by a distributor, all subsequent shipments inherently constitute "suspicious" orders. That assumption is inconsistent with the definition of a suspicious order as constituting orders of unusual size, pattern, or frequency. The absence of an investigation into an order that was "flagged" for some reason or another would not automatically make subsequent orders unusual in their size, pattern, or frequency. Subsequent orders might be of *lesser* sizes, *lower* frequency, or *different* patterns than the one that was "flagged" and thus would not constitute suspicious orders when viewed on their own merits.

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62 CAH_MDL2804_03263593 ("Cardinal Opioid Distribution Data")
63 McCann Report, ¶¶ 132, 136, 140, 144, 148.
64 Ibid.
65 Ibid.

57. To illustrate this point, consider a sequence of ten orders, only one of which exhibits an unusual size, frequency and/or pattern sufficient to trigger a particular methodology. If the flagged transaction occurs first in the sequence of ten orders, then McCann's approach would result in all ten orders being flagged as "suspicious" – the first based on the characteristics of the order, and the other nine solely because they came after that order. Had the sequence been reversed – with the "flagged" transaction occurring last – McCann's methodology would result in identifying only one of the ten orders (the last one) as suspicious based on the characteristics of that order. If it occurred somewhere in the middle, the number of "suspicious" orders would range from two through nine, depending solely on the sequence in which the orders occurred.

58. As an analytical exercise, McCann's approach more closely resembles a method of identifying a category of suspicious customers, if a suspicious customer is defined as one that at some point in time placed a single order of unusual size, pattern, or frequency (even if the customer showed no other sign of engaging in diversion). In McCann's analysis, subsequent orders from that customer are treated as suspicious not because of any characteristic of the order, but because the customer placing the order is inherently suspicious for all of its orders, regardless of their size, pattern, or frequency and regardless of whether the distributor believed the customer posed an unreasonable risk of diversion. I am not aware of any regulations that would indicate that this customer level restriction is required.

59. It is my understanding that most suspicious orders reported by registrants are individually small, on the order of one to three bottles per order flagged as suspicious.[66] Further, testimony from a designated representative of the DEA supports that even in the case of pharmacies that were "cut off" by a distributor, DEA anti-diversion personnel regarded those pharmacies as "legitimate" and took steps to avoid discouraging other distributors from fulfilling orders placed by those pharmacies "for legitimate medical purposes."[67] McCann effectively makes the inverse assumption that pharmacies with any prior order

[66] Deposition of Griffin, 1/23/2019, 181:15-182:12.

[67] Deposition of Howard, 4/25/2019, p. 47. One other DEA witness testified that he agreed with the statement that after an order had been blocked and reported as suspicious, a registrant "should terminate all future sales to that same customer until they can rule out that diversion is occurring." Prevoznik, 286:3-17 (However, the witness did not identify any DEA policy or regulation imposing such a requirement.).

that was flagged as "suspicious" are presumptively *illegitimate* as a result for all subsequent orders, regardless of the size of the original flagged order, and regardless of the individual characteristics of subsequent orders.

60. McCann's assumption is inconsistent with a standard articulated by Rafalski, who opines based on the *Masters* decision that "[o]nce a distributor has reported a suspicious order, it must make one of two choices: decline to ship *the order* or conduct some 'due diligence' and—if it is able to determine that *the order* is not likely to be diverted into illegal channels—ship *the order* (the Shipping Requirement)."[68] I do not offer an opinion on the validity of that assertion by Rafalski. Nevertheless, it can be observed that his standard places the focus on the order that was flagged as suspicious, not on additional orders by the same customer.

61. Similarly, McCann's methodology is circular in the sense that he is assuming that Cardinal (and the other distributors) did not systematically conduct due diligence of orders they did not flag as suspicious but that *he has flagged years after-the-fact*. Presumably McCann recognizes that because Cardinal was not using the same methods that he now uses, it would not have systematically flagged those orders for further review – and hence would not have conducted additional due diligence since they were not flagged in the first instance. McCann ignores that during the same time periods, Cardinal did flag *different* orders for review, and he fails to take into account any due diligence Cardinal conducted for orders from the same customers about which he is making this assumption.

62. As discussed below, McCann's methods ultimately identify [redacted] of Cardinal's customers as having at least one "suspicious" order, and all subsequent orders for that customer are identified as suspicious.

63. McCann's methods are improper to the extent he is suggesting that his retrospective methods, none of which were actually employed by Cardinal, can be superimposed as the methodology that Cardinal should have employed for the time period 1996 – 2017. For example, McCann's six-month trailing method is based on the 2017 Masters matter, concerning a different distributor's suspicious order monitoring ("SOM") system, which

[68] Rafalski, p. 9, 10 (emphasis added).

makes it difficult to fathom how it could have been required earlier or why it would be a required system for Cardinal. Multiple DEA deponents have stated that there is (still today) not a standard anti-diversion model that is required of all distributors. Former DEA Deputy Assistant Administrator Joseph Rannazzisi also stated that all that is required of a distributor is to establish an ADP with the ability to identify orders of unusual size, pattern, or frequency, and report them when identified.[69] Further, he said that only the distributor registrant can identify a suspicious order – not even the DEA can – because the registrant knows its customers. Application of McCann's methods is arbitrary, and an arbitrary method is not appropriate for identification of suspicious orders according to Rannazzisi, who stated, "DEA and our state partners have repeatedly and emphatically informed distributors that arbitrary thresholds are inappropriate, negatively impact legitimate patients, and are an inadequate substitute for fulfilling their obligations under the CSA."[70] Rafalski, McGuire, and Cutler endorse or rely upon McCann's six-month trailing method results as quantification of suspicious customer orders, but this is an improper application of a method that has no basis to be applied to Cardinal's historical distribution data.

64. Consistent with Rannazzisi's testimony, the methods identified by McCann are incapable of being "right" in any sense that makes all other methodologies actually employed by distributors "wrong." At best, they constitute additional methodologies by which, in McCann's view, a distributor could have undertaken to identify suspicious orders. But that is not a basis on which to say the methodologies actually employed by Cardinal or other distributors were unacceptable. McCann otherwise offers no opinion or analysis regarding the sufficiency of those methods.

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[69] Rannazzisi's 5/29/2015 response to 2015 GAO Report titled "Prescription Drugs: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access", p77-82 (https://www.gao.gov/assets/680/671032.pdf, accessed 5/9/2019) ("Rannazzisi Response to 2015 GAO Report").

[70] Rannazzisi Response to 2015 GAO Report, p77-82.

V. MCCANN'S REPORT INCLUDES MAJOR FLAWS THAT RENDER HIS RESULTS UNRELIABLE

65. McCann's Report describes three broad areas of work he performed at the request of counsel. The first area of work consisted of aggregating, reconciling and commenting on the overall completeness and validity of a synthesized dataset purported to represent, among other things, a complete record of all opioid shipments by Cardinal (and other distributors) to retail pharmacies in Summit and Cuyahoga counties during the period 1996 through May 2018. His second area of work involved running monthly patterns of opioid shipments by distributor and by retail pharmacy for twelve specific opiate related products through five distinct methods he designed to identify or "flag" orders that Rafalski concludes were shipped despite being suspicious. The final area of work involved comparing the proportion of orders identified as suspicious by any of his methods to the proportion of overall distributions in the state of Ohio that he deems to be "excessive" based on a separate analysis of aggregate ARCOS report data. McCann indicates this comparison is intended to test the reasonableness of the magnitude of shipments his methods identify as suspicious.

66. I have replicated each of the work areas described in McCann's report. I have identified some technical flaws in the work he did to create the synthesized data set and in his analysis; however, for the purposes of my analysis and in light of the major flaws in his approach, I have not addressed these technical flaws in this report.[71]

67. I have identified major flaws in McCann's approach to identify individual retail pharmacy shipments that he deems suspicious. As noted above, pharmaceutical distributors of controlled substances are required to design and implement a SOM system. McCann uses five distinct methods to flag orders that exceed set volume thresholds, but McCann does not describe if or when one method would be more useful than another method. However, Plaintiffs' expert Rafalski identifies McCann's six-month trailing method as providing a "reasonable estimate and an initial trigger and first step in identifying orders of unusual

[71] As of this report being submitted, I have not had a chance to review and incorporate any information from McCann's deposition, and I reserve the right to supplement my opinions including regarding his technical flaws as additional information becomes available.

size"[72] and Cutler and McGuire rely upon that same method for their calculations related to the portion alleged harm to the Plaintiffs and damages calculations, respectively.

68. Cutler relies upon McCann's six-month trailing method results as the basis for his estimate of the "share of harm" related to opioid use or abuse "potentially attributable to distributors" based on McCann's estimate of the share of excessive shipments that distributors fail to identify.[73] Cutler relies blindly on the McCann analysis[74] and uses the percentages to calculate harm caused by the distributor defendants. Therefore, the errors in McCann's approach with respect to Cardinal's opioid shipments have a significant downstream impact since Cutler uses those results to calculate the alleged harm to Plaintiffs in this matter. Cutler's results are then further used in McGuire's attempt to calculate alleged damages.[75] As described herein, Cutler and McGuire are relying upon a methodology that is wholly unreliable for the purpose of identifying suspicious orders.

69. Due to Plaintiffs' particular reliance on McCann's six-month trailing method, I will address that method first. Under this method, for each of the twelve opioid products addressed in his report, McCann flags all monthly shipment totals for each unique combination of distributor and retail pharmacy that exceed the maximum monthly shipments for that distributor/pharmacy combination from the preceding six months. Once one month's shipments for a particular drug/distributor/pharmacy combination is flagged, all subsequent orders are flagged as well. As it relates to Cardinal, McCann's use of this method results in [redacted] of orders, [redacted] of retail pharmacy customers, and [redacted] of dosage units being flagged as of suspicious. In my opinion, it is not reasonable to assume that [redacted] of the observed data points in any sequence of numbers represent "unusual" or "atypical" events.

70. McCann's identification under his six-month trailing method is flawed because it is inherently prone to flag a similarly large percentage of almost any numerical sequence to

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[72] See for example, Rafalski, p. 46. Rafalski indicates that he understands the results of the six-month trailing method will be used by another of Plaintiffs' experts to "measure the harm caused by this volume." As of the date of this report, only Cutler and McGuire have relied on the six-month trailing method. To the extent other of Plaintiffs' experts rely on the six-month trailing method, I reserve the right to supplement this report.

[73] Cutler Report, Appendix III.J, paragraph 4.

[74] Cutler deposition, p. 594 ("Q: Have you looked at Mr. McCann's report? A: I have not looked at Mr. McCann's report.").

[75] McGuire Report, ¶ 72.

which it is applied. The larger the number of possible outcomes for any one data point in a six-point data sequence, the higher the likelihood that the seventh data point in the series exceeds the maximum level of the preceding six data points in the series. For example, assume it is reasonable to expect that a particular pharmacy could "legitimately" order between 101 and 125 units of a particular opioid in any given month during a 250-month period. On average, the trailing six-month maximum method would be triggered between the 12th and 13th month of the 250-month period and would flag on average 96% of the total units, despite the fact that every order fell within the assumed reasonable range of 101 to 125 units.[76] Similarly, say the number of legitimate outcomes is reduced to 6 (e.g., the roll of a dice). On average the method would be triggered on the 16th or 17th roll of the dice and would flag 94% of the total units in a sequence of 250 dice rolls.[77] It is completely unreasonable to assume that 94% to 96% of the data points in any population are unusual or atypical. It is much more likely that the method being applied is not taking into account meaningful factors that contextualize the data points. McCann's method clearly creates the mistaken impression that a normal random distribution of expected outcomes represents excessive volumes, and he would like the reader to believe that these purported excessive volumes are representative of diversion into illicit drug channels.

71. If one introduces volume growth to the expected outcomes of the six-month trailing method, the likelihood increases that each passing month will be triggered by the method, as does the overall proportion of volume flagged by the method. So a pharmacy that is growing in general will have a greater tendency for orders to be flagged. Returning to the dice example, if the expected range of legitimate outcomes in month one is assumed to grow by 1% each subsequent month, the method would be triggered on average by roll number 9 or 10 (versus 16 or 17) and would result in more than 99% (versus 94%) of the total units being captured by roll 250.[78] As I will demonstrate later in this report, the volume

[76] These results are based on a Microsoft Excel spreadsheet model designed to generate 10,000 random sequences of 250 numbers, each between 101 and 125 (inclusive). I then applied McCann's six-month trailing method to each of the 10,000 sequences and determined the overall average.

[77] These results are based on a Microsoft Excel spreadsheet model designed to generate 10,000 random sequences of 250 numbers, each between 1 and 6 (inclusive). I then applied McCann's six-month trailing method to each of the 10,000 sequences and determined the overall average.

[78] These results are based on a Microsoft Excel spreadsheet model designed to generate 10,000 random sequences of 250 numbers, each between 1 and 6 (inclusive), growing at a rate of 1% per month. I then applied McCann's six-month trailing method to each of the 10,000 sequences and determined the overall average.

of legitimate prescriptions being written for opiate related products by licensed prescribers grew annually during the period 2006 through 2016. McCann's method fails to consider the effects of demonstrated growth in prescriptions to address a legitimate medical need.

72. In addition to normal volume growth, McCann's six-month trailing method fails to adjust for known and explainable trends or market changes. For example, in the dice scenario, if after the tenth roll one were to replace the standard cube with a cube that contained the values 11 and 16 on each side, the method would automatically be triggered by no later than the 11th roll and would flag, on average, over 99% of the total units.[79] This is due to the fact that the lowest value on the new cube (11) is inherently greater than the highest value on the original cube (6). This is directly relatable to Cardinal's distribution of hydrocodone, as I will address below.

73. To further demonstrate the fact that McCann's trailing six-month maximum method is destined to flag an overwhelming majority of practically every data sequence to which it is applied, I have applied it to Cardinal's shipped volume of various non-controlled substance drugs it distributed into Summit and Cuyahoga counties. Specifically, I have run the method for 10 top non-controlled products that Cardinal shipped in high volumes over the time period January 2006 – 2017. See Table 2 for the results by product.

[79] These results are based on a Microsoft Excel spreadsheet model designed to generate 10,000 random sequences of 250 numbers, with the first 10 months between 1 and 6 (inclusive) and all subsequent months between 11 and 16 (inclusive). I then applied McCann's six-month trailing method to each of the 10,000 sequences and determined the overall average.

Table 2: McCann's Methods Applied to Cardinal's Distributions of 10 Top Non-Controlled Substances (2006-2017)[80]

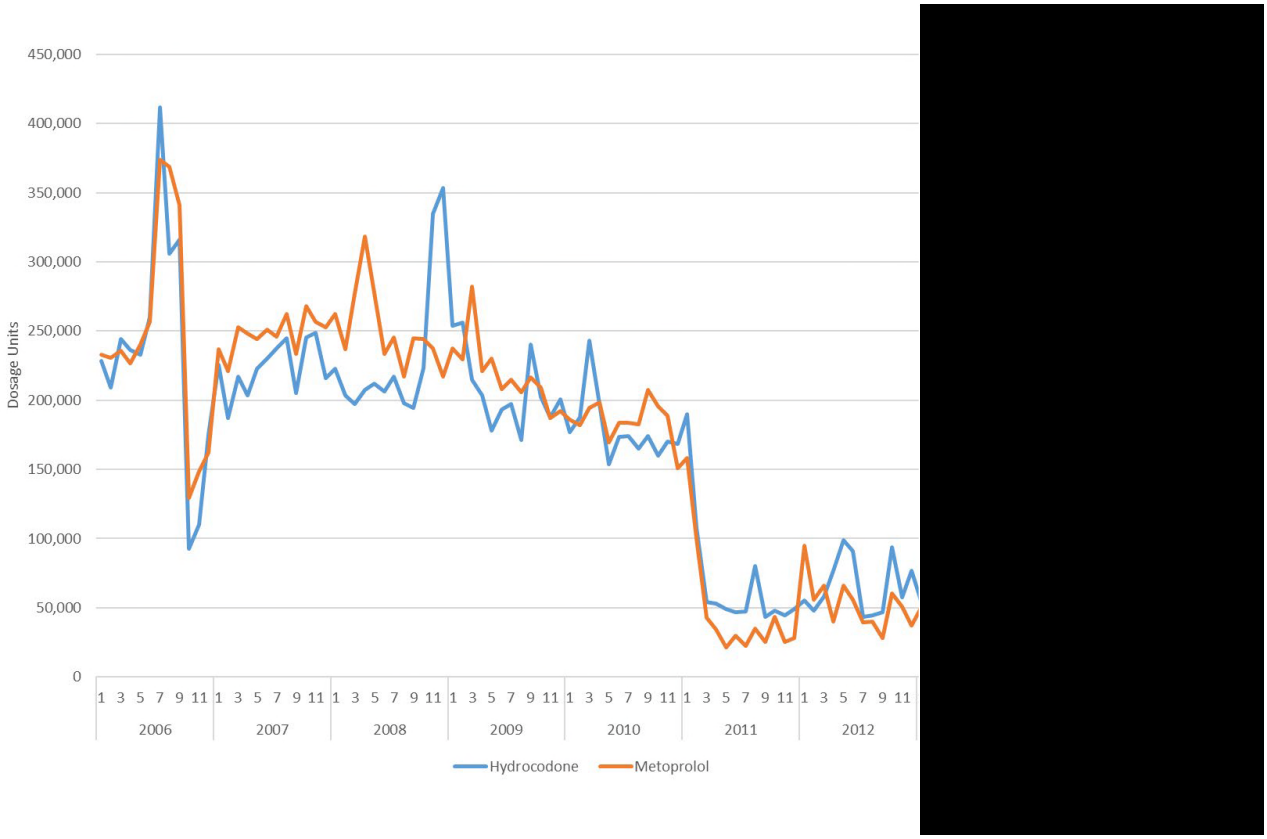
Ingredient Name	Description	% Flagged - Six-Month Trailing
Oxycodone	Opioid	[redacted]
Hydrocodone	Opioid	
Levothyroxine	Thyroid Medication, e.g. Synthroid, Tirosint	98.6%
Metoprolol	High Blood Pressure Medication, Beta-Blocker, e.g. Lopressor	97.7%
Lisinopril	High Blood Pressure Medication, ACE inhibitor, e.g. Prinivil, Qbr	97.8%
Metformin	Anti-Diabetic Medication, e.g. Glucophage, Glumetza	99.8%
Polyethylene Glycol 3350	Laxative, e.g. Miralax	92.3%
Atorvastatin	High Cholesterol Medication, e.g. Lipitor	88.9%
Hydrochlorothiazide	High Blood Pressure / Fluid Retention Medication, e.g. Microzid	96.1%
Atenolol	High Blood Pressure Medication, Beta-Blocker, e.g. Tenormin	96.1%
Furosemide	Diuretic, e.g. Lasix	94.9%
Cetirizine	Allergy Medication, e.g. Zyrtec	93.8%

74. Across all 10 of these non-controlled products, McCann's six-month trailing method flags an extremely high percentage of Cardinal's shipments of each drug, despite the absence of any reasonable expectation that diversion may be affecting the results. That is because there is nothing in the method that is discerning with respect to product diversion or suspicious orders, or really even whether an order is truly of "unusual size."

75. One of the 10 non-controlled products I analyzed is metoprolol, a commonly prescribed beta-blocker that treats high blood pressure, angina, and heart failure. In addition to 97.7% of shipments being flagged, it is interesting to note that metoprolol has a distribution trend very similar to a product McCann did analyze, hydrocodone (see Figure 2 below), and metoprolol would be flagged by McCann's method in a similar manner. The similarity in distribution patterns between metoprolol and hydrocodone is one more indicator that the shipments flagged are not suspicious orders with respect to size, pattern, or frequency – there is likely something else going on with respect to the ordering patterns.

[80] CAH_MDL2804_00617996, 00617997, 00059301, and 00618000 ("Cardinal Non-Opioid Distribution Data"); McCann Dataset; Elsevier Database. Includes pharmacy customers who purchase opioids in the period.
Elsevier Gold Standard Drug Database ("Elsevier Database") was used to extract NDCs relevant to the Non-Controlled Substances used in the analysis (See Appendix B). The Elsevier Database is a public, National Council for Prescription Drug Programs (NCPDP)-compliant database including U.S.-approved brand and generic prescription drugs, over-the-counter products, herbals, vitamins, and nutritional products, medical devices and diagnostic kits.

Figure 2: Total Hydrocodone and Metoprolol Dosage Units Shipped by Cardinal to Pharmacies (January 2006-September 2014)[81]



76. Table 3 presents a comparison of the results of applying McCann's methodology to the two products and the results are remarkably similar.

[81] Cardinal Non-Opioid Distribution Data; McCann Dataset; Elsevier Database. This analysis is limited to 2006-September 2014 so that the comparison is not impacted by the hydrocodone rescheduling in October 2014, which corresponds to an increase of hydrocodone distributions by Cardinal when it became the primary distributor of hydrocodone for pharmacies such as CVS and Discount Drug Mart. Includes pharmacy customers who purchased both hydrocodone and metoprolol in the period.

Table 3: McCann's Methods Applied to Cardinal Distributions of Hydrocodone and Metoprolol (2006-September 2014)[82]

McCann Method	Flagged Dosage Units		% Flagged Dosage Units	
	Hydrocodone	Metoprolol	Hydrocodone	Metoprolol
Six-Month Trailing	[redacted]	16,005,970	[redacted]	97.5%
Two Times Trailing Twelve-Month		13,802,670		84.1%
Three Times Trailing Twelve-Month		12,155,990		74.1%
8,000 Monthly Maximum		9,813,640		59.8%
Any McCann Method	[redacted]	*16,288,480*	[redacted]	*99.2%*

77. Rather than identifying any meaningful correlations between Cardinal's drug distribution patterns and potential instances of drug diversion, McCann's six-month trailing method describes the expected outcomes of nearly every sequence of data values, with a tendency to deliver skewed results when average expected values are growing. McCann did not look at Cardinal's opioid shipments at a customer level to test whether there are contextual factors that may explain individual Cardinal customer shipment patterns. I performed several analyses that do so, and those analyses contradict the results of the six-month trailing method as well as his other four methods, which generally fall prey to the same issue of McCann failing to consider customer specific factors in his assessment of Cardinal's shipments.

[82] Cardinal Non-Opioid Distribution Data; McCann Dataset; Elsevier Database. Analysis has been limited to 2006 – September 2014 to account for the rescheduling of hydrocodone. Includes pharmacy customers who purchased both hydrocodone and metoprolol in the period.

VI. MCCANN'S ANALYSIS IS FLAWED BECAUSE IT FAILS TO INCORPORATE CONTEXTUAL EVALUATION OF CARDINAL'S SHIPMENTS TO ITS CUSTOMERS

78. As described above, McCann's methods, for his six-month trailing method as well as the other four methods he executed, involve identifing transactions that meet certain criteria defined by McCann. This "blunt instrument" analysis includes no contextual analysis to determine if there are other circumstances that should be taken into consideration that may explain the shipment. In my opinion, it is necessary to perform a contextual analysis to look at other factors that may explain whether a transaction is truly unusual.

79. When I engage in contextual evaluation of McCann's customer-level results, I observe numerous factors that assist in evaluating whether a shipment is associated with a "suspicious order." For each of McCann's methods, I have performed certain contextual analyses on the shipments flagged by McCann. Based on the results on these analyses, which are described below, I conclude that contextual analyses on shipments flagged under McCain's method may have demonstrated that the shipments were not necessarily "suspicious orders."

80. The analyses described below are not an exhaustive list of the contextual analyses that could be applied to refine a customer specific analysis like those McCann purports to perform. However, it is clear from the results of the few analyses listed that McCann's failure to consider these factors has significantly affected the number of shipments flagged in his methods.

81. Table 4 summarizes each of the contextual analyses I performed and reports the percentage of shipments that were excessively flagged by McCann's methods.[83]

[83] As noted previously, because of Rafalski's, Cutler's, and McGuire's reliance on McCann's six-month trailing method, I have separated out the results for the six-month trailing method from the analysis of how many shipments are flagged by any of McCann's methods.

Table 4: Percentage of McCann Flagged Cardinal Dosage Units Affected by Contextual Analysis (2006-2017)

Contextual Analysis	Description	% of McCann's Six-Month Trailing Method (Dosage Units)	% of Any Method (Dosage Units)
Shipments captured by McCann "carry-forward" rule	Captured because a prior shipment violated the criteria (i.e., not based on the shipment itself)	94.3%	31.8%
Hydrocodone Rescheduling	Captured because no adjustment for hydrocodone rescheduling	5.0%	19.2%
Size of Pharmacy	Captured despite less than 22% of customer's shipped volume was controlled substances	84.0%	82.3%
Proximity to a Hospital	Captured despite pharmacy being located in close proximity to a hospital	26.9%	28.3%
Hospital Contractual Relationship	Captured despite pharmacy having a 340B relationship with hospital	8.6%	8.4%
Total Percentage of McCann's Analysis Affected by Contextual Analysis		**99.6%**	**95.5%**

A. Review Each Order as a Stand-Alone Shipment

82. As described above, each of McCann's methods identifies not just shipments above his defined threshold for the month being analyzed, but also all subsequent shipments for a

customer after a single flagged shipment.[84] For instance, if a shipment in January 2006 exceeded the volume threshold identified by McCann's method, all subsequent shipments of that drug to the same customer are flagged. This "carry-forward" assumption drives a majority of McCann's flagged shipments under the six-month trailing method, over 94% of which would fall below his monthly thresholds if evaluated on a monthly basis.[85]

83. To quantify the effect of this assumption on McCann's results, I have implemented his methods without the carry-forward assumption (i.e., only identifying the particular shipments that would be above the monthly thresholds). The results indicate that in many cases, McCann is not identifying "orders of unusual size;" rather, he is flagging customers and capturing all of their product shipments after a certain date. For example, the results of the six-month trailing method appear to identify a large number of shipments exceeding the identified threshold, however, when the carry-forward rule is eliminated, even under McCann's methodology, only about 5% of Cardinal doses shipped would be identified. Table 5 below describes the impact of removing the carry-forward rule for each of McCann's methods.

Table 5: Comparison of Percentage of Cardinal Transactions Flagged When Removing Carry-Forward (2006-2017)[86]

McCann Method	% Flagged - McCann Method	% Flagged - Remove Carry-Forward	% of McCann Flagged Dosage Units Affected
Six-Month Trailing	[redacted]	[redacted]	94.3%
Two Times Trailing Twelve-Month	[redacted]	[redacted]	72.6%
Three Times Trailing Twelve-Month	[redacted]	[redacted]	78.3%
8,000 Monthly Maximum	[redacted]	[redacted]	57.8%
Maximum Daily Dosage Units	[redacted]	[redacted]	37.4%
Any McCann Method	[redacted]	[redacted]	*31.8%*

84. An issue specific to Cardinal is that the company produced data back to 1996 whereas complete data is not consistently available for other distributors until 2006. Because

[84] "In this approach and the others implemented below I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged." McCann Report, ¶¶ 132, 136, 140, 144, 148.

[85] See Table 5.

[86] McCann Dataset.

Cardinal produced data for the longest time period, it is disproportionately affected by McCann's carry-forward rule. I have analyzed how many of McCann's flagged shipments were included because of the carry-forward rule being applied to flagged shipments from prior to 2006. Prior to 2006, 5.3% of dosage units flagged by McCann's six-month trailing method are because of McCann's carry-forward rule. Adjusting McCann's methods to start in 2006, and still including his carry-forward rule, results in a lower percentage of doses being identified across all five methods. For example, under the three times trailing twelve-month method, 45.7% of McCann's analyzed orders would have been flagged from 2006 forward compared to 57.6% if 1996 forward is included. Table 6 summarizes the impact of starting McCann's methods for Cardinal in 1996 versus 2006.

Table 6: Comparison of Percentage Flagged When Applying Methods Starting in 1996 vs 2006[87]

McCann Method	% Dosage Units Flagged Based on Data Beginning in 1996	% Dosage Units Flagged Based on Data Beginning in 2006
Six-Month Trailing	92.9%	87.6%
Two Times Trailing Twelve-Month	79.6%	68.8%
Three Times Trailing Twelve-Month	57.6%	45.7%
8,000 Monthly Maximum	70.5%	69.2%
Maximum Daily Dosage Units	93.6%	91.7%
Any McCann Method	*98.0%*	*96.1%*

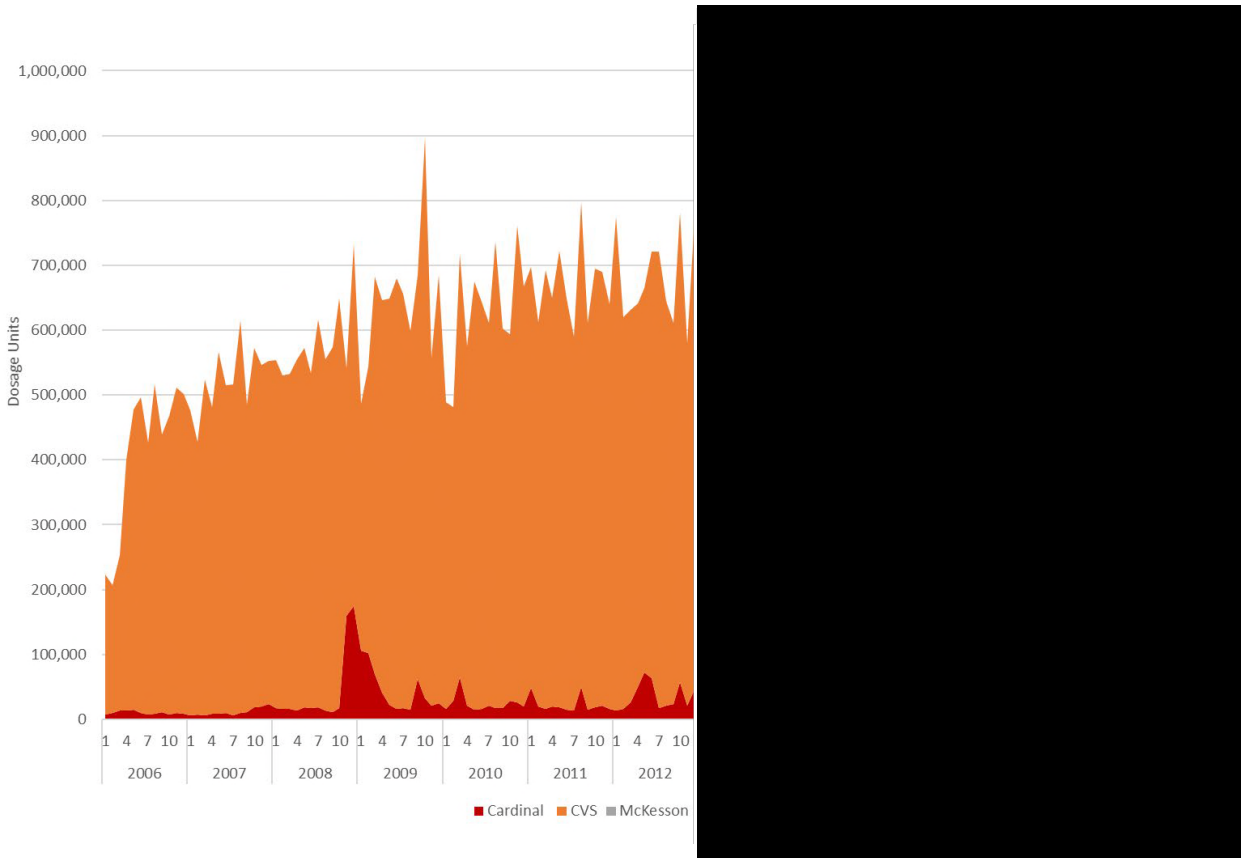
B. Hydrocodone Rescheduling

85. McCann's identification of shipments does not take into account the rescheduling of hydrocodone and how this event led to a change in how the product was distributed to many pharmacies. In 2014, hydrocodone was rescheduled from Schedule III to Schedule II. When hydrocodone was a Schedule III product, most large chain pharmacies (for example, Cardinal's customer CVS), used their own chain warehouses as the primary supplier of hydrocodone to their pharmacies. After the rescheduling, many chain

[87] McCann Dataset numbers reported for 2006-2017 are used for both calculations, however, initial flagging and carry-forward begin in 1996 and 2006, respectively.

warehouses no longer maintained hydrocodone inventory or shipped the product.[88] Cardinal became the primary supplier of hydrocodone to some chain pharmacies for which it had previously been a secondary distributor, including for its largest customer, CVS. See Figure 3 for a comparison of the hydrocodone volume shipped to CVS pharmacies by Cardinal vs. CVS over time; it is clear that the rescheduling in 2014 is a unique event that warrants consideration in an analysis of shipment patterns. Not surprisingly, that change caused a large spike in shipped volume of hydrocodone by Cardinal to customers like CVS pharmacies. 100% of these shipments were flagged as suspicious either because of the carry-forward rule or because of the large increase in dosage units being shipped.

Figure 3: All Hydrocodone Shipments to CVS Pharmacies by Distributor (2006-2017)[89]



[88] ARCOS data. Also see discussion above regarding storage requirement differences in Schedule II versus Schedule III products. The additional regulations around storage and shipment of Schedule II products was a contributing factor to chain pharmacies discontinuing their fulfillment of hydrocodone.

[89] McCann Dataset.

86. I noted that McCann's methods were all programmed such that they "reset" when a customer changed distributors, but the methods did not account for a shift in distributor relationships such as these shifts from being a secondary distributor to primary. In my opinion, that new primary distributor relationship should be evaluated separately from the previous secondary distributor relationship. McCann's failure to incorporate the context of the hydrocodone orders causes him to overstate the dosage units flagged his six-month trailing method by 5% (across all products).

87. I have quantified the impact the hydrocodone rescheduling had on McCann's six-month trailing method in the table below. This issue also affects his two times and three times trailing twelve-month methods.

Table 7: McCann's Methods Accounting for Hydrocodone Rescheduling in Cardinal's Distributions (2006-2017)[90]

McCann Method	% Flagged Hydrocodone by McCann	% Flagged - Accounting for Hydrocodone Rescheduling	% of McCann Flagged Dosage Units Affected
Six-Month Trailing	[redacted]	[redacted]	5.0%
Two Times Trailing Twelve-Month	[redacted]	[redacted]	8.8%
Three Times Trailing Twelve-Month	[redacted]	[redacted]	14.1%
8,000 Monthly Maximum	[redacted]	[redacted]	0.0%
Maximum Daily Dosage	[redacted]	[redacted]	0.0%
Any McCann Method	[redacted]	[redacted]	*19.2%*

C. Size of Pharmacy

88. McCann's methods are not sophisticated enough to account for the size of the pharmacies in his analysis. He treats a small independent pharmacy with very little foot traffic and relatively few patients the same as a large chain pharmacy, such as CVS. Obviously, size matters when looking at order volumes and this flaw in McCann's methodology has a

[90] McCann Dataset; CVS and Discount Drug Mart were treated as new customers starting after the hydrocodone rescheduling and compared to the combination of the CVS and Discount Drug Mart distributions from Cardinal and the CVS/Discount Drug Mart warehouses for the period prior to the hydrocodone rescheduling.

material impact on his results, causing him to flag shipments as suspicious when, put in context, there is no reason to consider them to be of "unusual size."[91]

89. One way we typically deal with different sized subjects in analyses is to create a metric that normalizes the variable we are interested in. In this case, an examination of opioid distributions to Cardinal's customers can be put in context of the total drug distributions to those customers. Total drug distributions serve as a reasonable measure of the overall size of a pharmacy, as it reflects the volume of all drug products the pharmacy dispenses, including non-controlled substances. The DEA has acknowledged that the ratio of controlled substances to total product volume ("CS %") is a relevant factor for distributors to consider in assessing pharmacy orders of controlled substances and has indicated that a 20 percent CS % was common, and sometimes a higher percentage could exist for a legitimate pharmacy.[92]

90. In the 2007 *Southwood* decision identified by Rafalski in his report, Mike Mapes, Chief of the Office of Diversion Control's E-Commerce Section, stated, for a "typical" retail pharmacy in 2006 "controlled substances might amount to between five and twenty percent of the pharmacy's purchases'' with the other eighty to ninety percent of its purchases being non-controlled drugs."[93] That same statistic was mentioned in the Masters administrative decision that McCann cites for his six-month trailing method.[94] DEA employee Kyle Wright indicated in his deposition in this matter as follows: "Q: And is it accurate to say that you knew it was common for legitimate pharmacies to have a ratio of approximately 20 percent of controlled to 80 percent noncontrolled? A: In that area, yes. Q: Okay. And higher percentages of controlled drugs could be reasonable at times, right? A: Yes."[95]

91. In order to account for pharmacy size, I calculated the percentage of total shipments to a customer that were controlled substances (CS %) or opioids ("Opioids %"). These percentages control for pharmacy size by comparing the pharmacy's demand for controlled

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91 State of Ohio Board of Pharmacy, FAQ: Suspicious Order Monitoring and Due Diligence, found at https://www.pharmacy.ohio.gov/Documents/Pubs/Special/SUSPICIOUS_ORDER/Suspicious%20Order%20Monitoring%20and%20Due%20Diligence.pdf, last accessed 5/8/2019.
92 Deposition of Kyle Wright, 2/28/2019 ("Wright Deposition"), 260:13-22.
93 Southwood Pharmaceuticals, Inc. Revocation of Registration, 72 Fed. Reg. 36492 (July 3, 2007).
94 Masters Pharmaceuticals, Inc. Decision and Order, 80 Fed. Reg. 55477 (September 15, 2015).
95 Wright Deposition, p. 260.

substances (or opioids) to its overall demand for drug products. Using distribution data produced in this litigation by Cardinal and CVS,[96] I calculated the CS % and Opioids % of total shipments for each of Cardinal's Cuyahoga and Summit County pharmacy customers included in McCann's analysis.[97] Table 8 shows that the aggregate controlled substances percentage across customers for 2006 – 2017 was ~[redacted] and the aggregate opioids percentage was [redacted]. CVS pharmacies overall had a CS % of [redacted] I have also listed the top 7 CVS pharmacies by volume, which reveals a range of CS % from [redacted] to [redacted] The Opioids % (a subset of the CS %) ranges from [redacted] to [redacted].[98]

Table 8: Controlled Substance and Opioid Concentration to Cardinal Track 1 Customers (2006-2017)[99]

Customer(s)	Controlled Substance %	Opioid %	Six-Month Trailing % Flagged	Any Method % Flagged
McCann Customers	[redacted]	[redacted]	[redacted]	[redacted]
CVS	[redacted]	[redacted]	[redacted]	[redacted]
CVS #3322	[redacted]	[redacted]	[redacted]	[redacted]
CVS #4800	[redacted]	[redacted]	[redacted]	[redacted]
CVS #4347	[redacted]	[redacted]	[redacted]	[redacted]
CVS #3035	[redacted]	[redacted]	[redacted]	[redacted]
CVS #3360	[redacted]	[redacted]	[redacted]	[redacted]
CVS #4300	[redacted]	[redacted]	[redacted]	[redacted]
CVS #3338	[redacted]	[redacted]	[redacted]	[redacted]
All Other Customers	[redacted]	[redacted]	[redacted]	[redacted]

[96] Cardinal serviced the majority of Track 1 CVS pharmacies' controlled substance volume during the relevant time period while CVS chain warehouses serviced their pharmacies for non-controlled substances. Cardinal only accounted for about [redacted] of the total volume shipped to CVS pharmacies; Therefore, using just the data available to Cardinal does not capture the full story of each CVS pharmacy's controlled substance concentration.

[97] Note that Cardinal does not have access to the CVS data in real time. I was only able to perform the CVS calculations due to the production of data that CVS made in this matter.

[98] Note that the % flagged by McCann sometimes exceeds 100%. This is due to shipments that were returned but still flagged by McCann.

[99] McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS_MDLT1_000124148-000124180 ("CVS Distribution Data").
To convert the Cardinal Non-Opioid Distribution Data to dosage units, I have performed the following calculation: Size * Quantity Shipped. To convert the CVS Distribution Data to dosage units, I have performed the following calculation: Size * Regular Quantity. See State of Ohio Board of Pharmacy, FAQ: Suspicious Order Monitoring and Due Diligence, p8, found at https://www.pharmacy.ohio.gov/Documents/Pubs/Special/SUSPICIOUS_ORDER/Suspicious%20Order%20Monitoring%20and%20Due%20Diligence.pdf, last accessed 5/8/2019.

92. Table 8 also reflects the percentage of opioid dosage units flagged by McCann's six-month trailing method and any method. Regardless of whether a pharmacy's CS % was [redacted] or [redacted], or whether opioids accounted for [redacted] or [redacted] of a CVS pharmacy's dosage units, McCann flags [redacted] or more of the shipments under his six-month trailing method and over [redacted] under any method.

93. I analyzed the annual CS % of CVS pharmacies in Track 1. I found that the CS % for these CVS pharmacies generally remained at or below [redacted] for the years 2006 – 2017. For pharmacies with higher percentages, additional reasons for those higher percentages may exist such as customer location (e.g., being near a hospital, cancer clinic, in a rural areas, etc.), the population serviced by the pharmacy, or other factors.[100] An understanding of these reasons is usually related to a distributor knowing its customer and tailoring the threshold limits for the customer based on the customer's routine usage of controlled substances. Additional information about my analysis can be found in Appendix C.[101]

94. To further test my conclusion that McCann's methods are biased toward flagging large pharmacies, I broke the CVS pharmacies into three groups by total shipments (small, medium, and large). Table 9 shows that while CS % and Opioid % are generally consistent across the three groups, the percentage flagged by McCann increases with the size of the pharmacy. In other words, McCann's methods are more likely to identify opioid shipments to large CVS pharmacies as outliers despite the fact that these pharmacies are purchasing a similar volume of opioids relative to their size as compared to the small and medium CVS pharmacies.

[100] Rannazzisi Deposition, 274:10-275:3; Wright deposition, 260:13-25; Ashley Deposition, 150:13-151:17; see also Consensus Document, Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, found at https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf, last accessed May 8, 2019.

[101] Additionally, Appendix C presents the same summary for Opioids %.

Table 9: Strata Analysis of Flagged Cardinal CVS Pharmacies (2006-2017)[102]

Total Volume Percentile Buckets	Controlled Substance %	Opioid %	Six-Month Trailing % Flagged	Any McCann Method %
Small Volume CVS Stores	[redacted]	[redacted]	[redacted]	[redacted]
Medium Volume CVS Stores				
Large Volume CVS Stores				
Overall	*12*	[redacted]	[redacted]	[redacted]

95. I have quantified the percentage of dosage units that McCann flagged that are associated with customers that had an annual CS % of 22% or less. The 22% threshold for this analysis is conservative given the DEA's characterization that 20% may be indicative of a "common" or "typical" pharmacy and that higher percentages may be expected for some pharmacies depending on other characteristics.[103, 104] The use of 22% is not meant to imply that anything over 22% is suspicious; rather, there may be other factors that one would have to consider before determining an order was suspicious.[105] Even before such consideration, [redacted] of the McCann flagged dosage units are affected by this analysis.

[102] McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS Distribution Data.
CVS small, medium, and large customers have been categorized based on total distributions between the 0-25th, 25th-75th, and above the 75th percentiles, respectively.

[103] Wright Deposition, 260:13-261:1.

[104] I used 22% based on applying a 10% increase over the 20% CS % that DEA indicated would be typical for a pharmacy. If 20% is typical, then an unusual high percentage would be materially higher than 20%.

[105] Wright Deposition, 260:19-261:1 (recognizing that percentages of controlled substances over 20% may be reasonable at times, such as situations when a pharmacy is located next to a cancer clinic).

Table 10: Percentage of McCann Flagged Cardinal Dosage Units with CS % Less than 22% (2006-2017)[106, 107]

McCann Method	% Flagged - McCann Method	% of McCann Flagged Dosage Units Affected
Six-Month Trailing	[redacted]	[redacted]
Two Times Trailing Twelve-Month		
Three Times Trailing Twelve-Month		
8,000 Monthly Maximum		
Maximum Daily Dosage Units		
Any McCann Method	[redacted]	[redacted]

D. Consider Proximity to a Hospital

96. As mentioned above, another factor that could affect the volume of opioids purchased by one of Cardinal's customers is proximity to, or relationship with, a hospital or other clinical location that writes prescriptions for opioids.[108] Joseph Rannazzisi, who was the head of the DEA's Office of Diversion Control from 2005 – 2015, testified in response to a question about the level of due diligence performed by a distributor, "[i]t depends on the type of due diligence they're doing on their customers; whether they know their customers and what their customers' normal ordering patterns are; where is their customer situated; is the customer closer to a hospital; is the customer close to – is in a rural areas. There are so many dynamics that the drug enforcement administration doesn't have. Only the business, the distributor, the registrant has that information."[109]

97. For all five of his methods, McCann explicitly excludes hospital customers from his analysis. McCann's excludes of hospital customers, however, does not account for the volume of hospital prescriptions referenced by the DEA witnesses – prescriptions filled at separate on-campus, outpatient pharmacies or pharmacies within a close proximity to a

106 McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS Distribution Data.
107 I have also calculated 20 % CS or 25 % CS using McCann's six-month trailing and any method. McCann six-month trailing: 20% CS-[redacted] and 25% CS-[redacted]; any method: 20%[redacted] and 25% CS[redacted]
108 Deposition of Emma Douglas, 1/17/2019, 121:6-126:10.
109 Rannazzisi Deposition, 274:10-275:3.

hospital. For example, McCann excludes from his analysis shipments by Cardinal to the MetroHealth system but includes shipments to MetroHealth pharmacy, which is an onsite pharmacy on the MetroHealth campus. As such, McCann's analysis does not appropriately account for pharmacies that would tend to dispense more controlled substances because of their proximity to a hospital.[110]

98. To account for a pharmacy's proximity to a hospital, I determined the number of shipments flagged by McCann that were sent to a pharmacy close to a hospital.[111] A pharmacy was considered close to a hospital if it was within 0.25 miles of a hospital or was the closest pharmacy to a hospital regardless of distance (to account for the less concentrated areas of Cuyahoga and Summit counties). Some of these pharmacies (such as the MetroHealth example cited above) are in the same building or on the same campus as the hospital. Another example is New Choice Pharmacy, which was on-site at Western Reserve Hospital in Cuyahoga Falls. Cardinal documented in 2008 that New Choice was owned by the hospital and serviced oncology and hospice patients, noting that as a rationale for an opioid threshold exception.[112] Others are within blocks of the facility. For example, CVS Store #4800 is across the street from Summa Health System's Akron Campus.

99. In total, over [redacted] of the opioid doses flagged by McCann were shipped to pharmacies that were either on-site [redacted] or otherwise within close proximity to ([redacted] a hospital. Table 11 summarizes the percentage of McCann's flagged shipments under each of his methods sent to pharmacies within a close proximity to a hospital.

[110] Ibid.
[111] Close proximity to a Hospital has been defined as on-site at hospital, within 0.25 miles of a hospital, or the nearest pharmacy to a hospital.
[112] 01_CAH_MDL2804_00000605_CAH_MDL_2804_002.pdf

Table 11: Percentage of McCann Flagged Cardinal Dosage Units within Close Proximity to Hospital (2006-2017)[113]

McCann Method	% of McCann Flagged Dosage Units Affected
Six-Month Trailing	26.9%
Two Times Trailing Twelve-Month	28.8%
Three Times Trailing Twelve-Month	31.6%
8,000 Monthly Maximum	27.6%
Maximum Daily Dosage Units	28.1%
Any McCann Method	*28.3%*

E. 340B Pharmacies

100. In addition to the pharmacies within close proximity to a hospital, some pharmacies have contractual relationships with hospitals that could affect customer demand for covered products including opioids. Several hospitals in Cuyahoga and Summit county are enrolled in the 340B discount drug program, which is a program through which those facilities can access prescription drugs at discounted prices.[114] Hospitals eligible for participation include disproportionate share (DSH) hospitals, children's hospitals, and others. Starting in 2010, an increasing number of 340B hospitals began dispensing products not only through their outpatient pharmacies, but also through community retail pharmacies. McCann includes these community retail pharmacies in his analysis.

101. There are 86 pharmacies in Cuyahoga and Summit counties that were 340B contract pharmacies during at least some portion of the relevant time period for McCann's methods. To account for these pharmacies, I identified 340B contract pharmacies in the Track 1 counties and isolated the opioid dosage units flagged related to those pharmacies at the

[113] McCann Dataset; ARCOS; Texas A&M University GeoInnovation Center; TAMU GeoServices. Available at https://geoservices.tamu.edu/ (Accessed 5/8/2019). Close Proximity to a Hospital has been defined as on-site at hospital, within 0.25 miles of a hospital, or be the nearest pharmacy to a hospital.

[114] These designated 340B contract pharmacies dispense outpatient drugs on behalf of the 340B covered entity (hospital). http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0f (Accessed 5/9/2019).

time they were 340B contract pharmacies. Those dosage units totaled 8.6% for the six-month trailing method and 8.4% in any method.

Table 12: Percentage of McCann Flagged Cardinal Dosage Units for 340B Contract Pharmacy (2006-2017)[115]

McCann Method	% of McCann Flagged Doses Affected
Six-Month Trailing	8.6%
Two Times Trailing Twelve-Month	7.5%
Three Times Trailing Twelve-Month	7.2%
8,000 Monthly Maximum	8.7%
Maximum Daily Dosage Units	8.6%
Any McCann Method	*8.4%*

[115] McCann Dataset; National Counsel for Prescription Drug Programs dataQ (https://ncpdp.org/Products, accessed 5/9/2019); Office of Pharmacy Affairs Contract Pharmacy dataset (https://340bopais.hrsa.gov/(X(1)S(5w3flj0ycfsvkf2myp4uoo5g))/reports, accessed 5/9/2019). 340B Contract Pharmacies are pharmacies with active 340B contract at the time of the distribution.

102. In summary, 99.6% of McCann's six-month trailing method is affected by my contextual analysis (95.5% across all methods).

Table 13: Percentage of McCann Flagged Cardinal Dosage Units Affected by Contextual Analysis (2006-2017)

Contextual Analysis	Description	% of McCann's Six-Month Trailing Method Dosage Units	% of Any Method Dosage Units
Shipments captured by McCann "carry-forward" rule	Captured because a prior shipment violated the criteria (i.e., not based on the shipment itself)	94.3%	31.8%
Hydrocodone Rescheduling	Captured because no adjustment for hydrocodone rescheduling	5.0%	19.2%
Size of Pharmacy	Captured despite less than 22% of customer's shipped volume was controlled substances	84.0%	82.3%
Proximity to a Hospital	Captured despite pharmacy being located in close proximity to a hospital	26.9%	28.3%
Hospital Contractual Relationship	Captured despite pharmacy having a 340B relationship with hospital	8.6%	8.4%
Total Percentage of McCann's Analysis Affected by Contextual Analysis		**99.6%**	**95.5%**

VII. MCCANN'S ANALYSIS FAILS TO CONSIDER MARKET LEVEL FACTORS THAT EXPLAIN CARDINAL'S SHIPMENT TRENDS

A. McCann's Excessive Shipment Analysis

103. In Section X of his report, McCann attempts to support his methods for identifying shipments of unusual size by performing a high-level analysis of what he terms "excessive shipments." McCann bases his excessive shipments analysis on ARCOS reported data for the state of Ohio from 1997 – 2018. He uses annual morphine milligram equivalents (MME) per capita in the state to identify two different baseline assumptions for "legitimate opioid use." McCann's Figure 24 depicts his methodology in terms of Ohio MME per capita, which is recreated below as Figure 4 for ease of discussion.

104. The first baseline assumes that all opioid prescriptions in 1997 represent "medically necessary" opioid use and any opioid use beyond this level in 1998 – 2017 may be unnecessary. McCann references this baseline as "a possible lower bound" of medically necessary opioid MME per capita. This line is identified as the purple dashed line in Figure 4 below and the area shaded gray represents the volume of MME which McCann deems the lower limit of medically necessary use.

105. McCann creates a second so-called baseline by assuming that: (1) the drivers for opioid use evolve gradually over time, and (2) all (100%) opioid prescriptions in 2018 represent "medically necessary" opioid use. McCann does not explain why he selected 1997 or 2018 for the analysis and uses these unsupported assumptions to suggest creating an interpolated baseline from 1997 to 2018. This line is identified as the gray dotted line in Figure 4 below and the areas shaded gray and yellow represents the volume of MME which McCann deems the upper limit of medically necessary use.

106. McCann opines that any opioid use above these baselines represent possible unnecessary opioid use, which he estimates to be between 58.6%-77.3%[116] of total MME shipped into Ohio from 1998 to 2017.[117]

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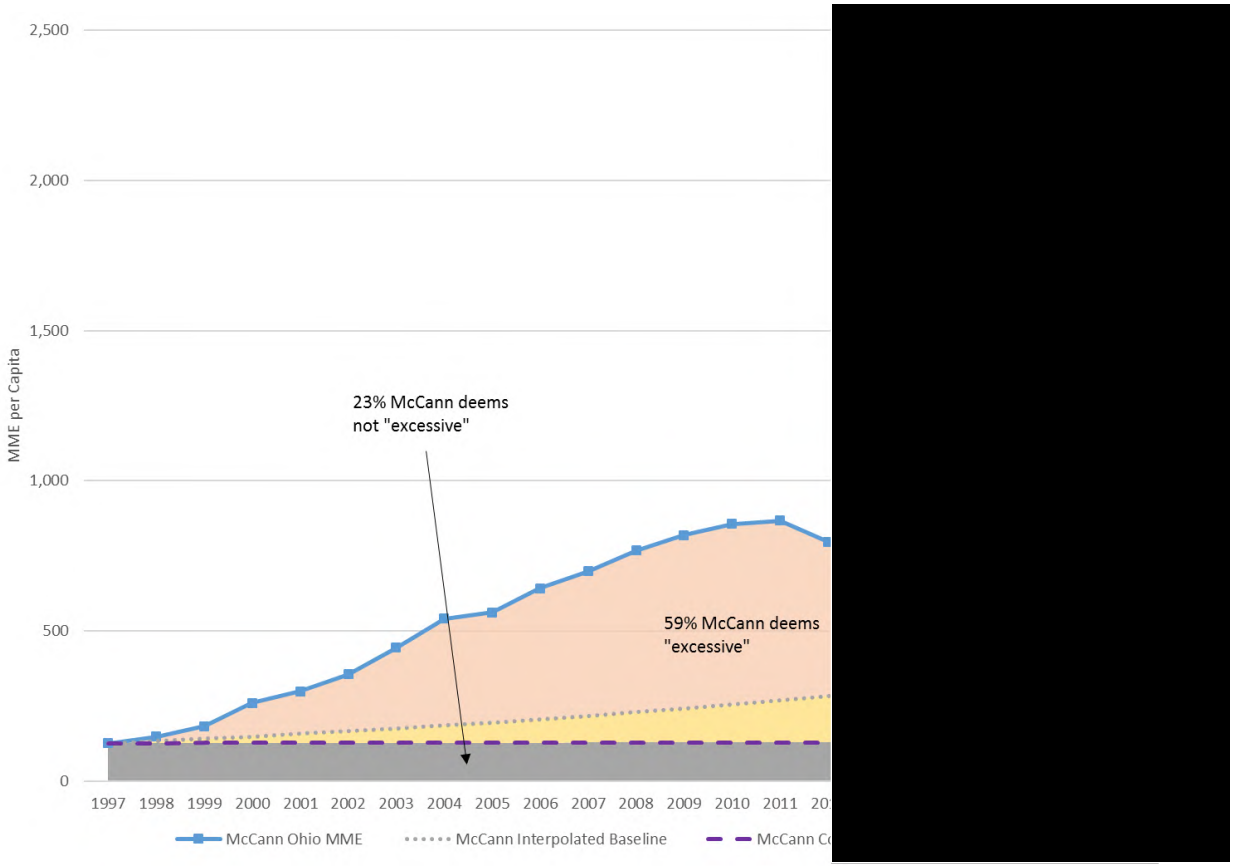
[116] The salmon shaded area on Figure 4 equals 58.6% of the total MME volume. The salmon and yellow shaded areas represent 77.3% of the total MME volume.

[117] McCann Report, ¶ 158.

107. McCann does not define what is meant by "medically necessary" and provides no rationale to support why opioid prescription volume in 1997 or 2018 would be instructive in identifying excessive shipments. As such, there is no basis to assume or conclude that opioid prescription volume in 1997 or 2018 is relevant to McCann's analysis. Despite this fundamental lack of foundation to support his analysis, to the extent McCann's excessive shipment analysis is understood, I disagree that either baseline is related or helpful to identify medically necessary opioid use or excessive shipments.

Figure 4: Comparison of McCann Baselines and Ohio Distributions (1997 -2018)[118]



108. In an effort to capture additional shipments as "excessive," McCann opines that because there is an overall decline in opioid use from 2012 to 2018, his use of 100% of the 2018 prescription volume to create the upper bound likely overestimates "legitimate opioid use." In Table 45 of McCann's Report, he attempts to adjust for this overall decline in opioid use

[118] McCann Report, Table 44.

by calculating the excessive MME shipped if the percentage of "legitimate" opioid use is less than 100% of the 2018 level (i.e., 0%, 20%, 40%, 60%, and 80%).[119] McCann does not opine on which, if any, of these percentage reductions would be an accurate assumption of unnecessary growth.

109. In sum, McCann does not describe or support how his seemingly random baselines are appropriate to estimate or form conclusions regarding unnecessary opioid use. As described in more detail below, McCann's unsupported conclusions also conflict with (1) a comparison of opioid distributions in Ohio; (2) the prescription demand for opioids; and (3) opioid production levels deemed appropriate by DEA over the relevant time period.

B. Shipments in View of Legitimate Patient Need

110. As illustrated in Figure 1 above (¶ 32), a doctor can order a controlled substance be provided to a patient to address a legitimate patient need by writing a prescription for the patient. The patient presents the prescription at the pharmacy for fulfillment. In response to receiving a prescription; the pharmacy places orders for the prescribed controlled substance, causing the distributor to ship the ordered controlled substance to the pharmacy. It is not proper to make a sweeping conclusion that large numbers of shipments are "unnecessary" without information about the legitimate patient need to be addressed by the prescribed controlled substance. Indeed, "DEA presumes [ ] that most physicians provide appropriate amounts of pain medication."[120] As such, an inquiry into the legitimate medical purpose underlying the use of the controlled substance is required before a prescription can be deemed "unnecessary."

111. Figure 5 below compares opioid distributions in Ohio (using MME per capita; represented by the blue line) to nationwide MME per capita usage as determined by prescription data (using MME per capita; represented by the orange line).[121] As described above, the use of

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[119] McCann Report, ¶ 159.

[120] DEA Statement on Dispensing Controlled Substances for the Treatment of Pain (2006), p. 4. (https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm, accessed 5/9/2019).

[121] The data used for prescription MME reflects prescription data from IMS that has been converted to MME per capita by dividing by the 2010 US population per the United States Census Bureau ("Census"). Summary data was found here: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2728005 (accessed 5/9/2019) ("IMS Data"). IMS (Information Medical Statistics), which is now known as IQVIA, is the largest vendor of

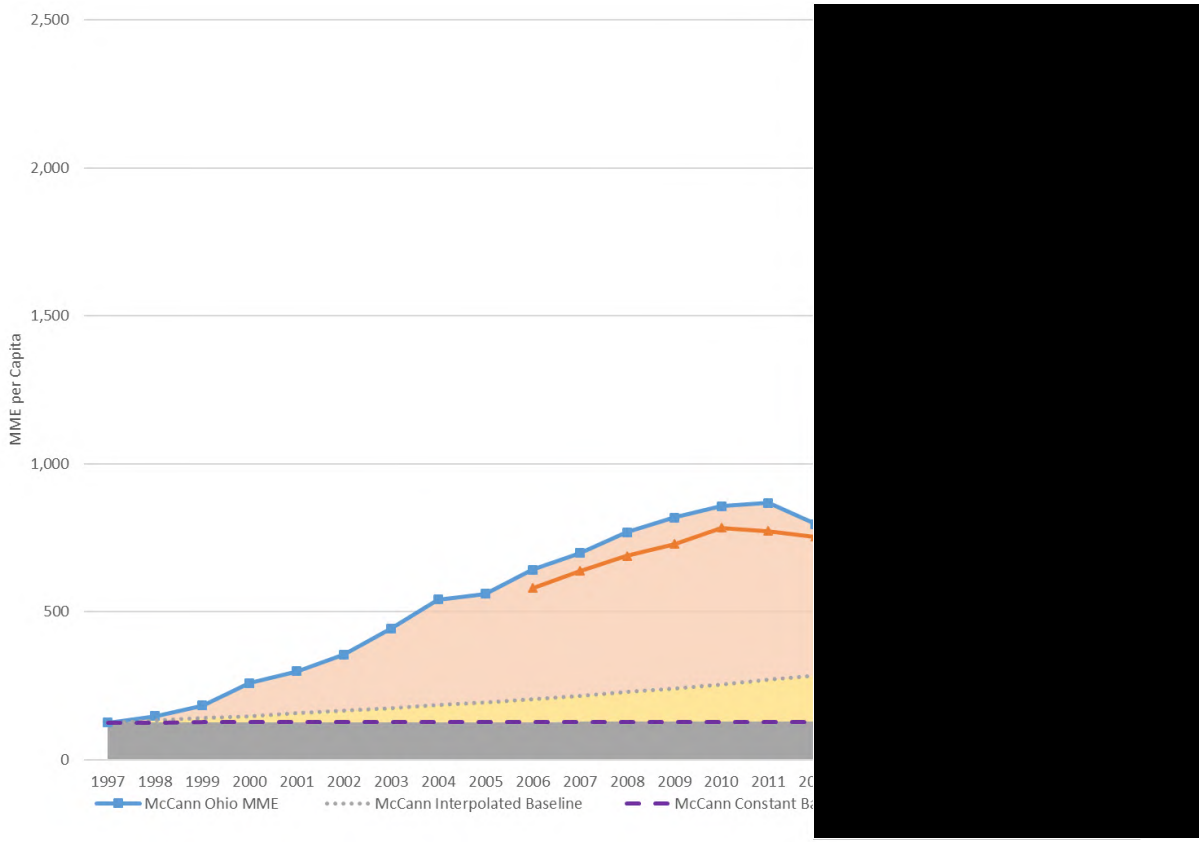
IMS prescription data allows a comparison of the volume of prescribed controlled substances (i.e., what the doctor has ordered as appropriate for a legitimate medical need) versus controlled substance shipments to pharmacies (used to fill the prescription orders). The appropriateness of using prescribing trends to evaluate legitimate medical use of controlled substances is well supported by the DEA's recognition that "the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes."[122]

112. The comparison in the figure below demonstrates that shipments of opioids into Ohio were consistent with the overall nationwide prescription volume for opioids. Thus, the legitimate patient need, as determined by a licensed prescriber, for opioids in Ohio was similar to the nationwide need, and it is reasonable to conclude that the shipments into Ohio were not necessarily excessive. In addition, the comparison further illustrates that the theoretical baseline values constructed by McCann are not consistent with specific market data for the relevant time period.

U.S. physician prescribing data. The firm has "one of the largest and most comprehensive collections of healthcare information in the world, spanning sales, prescription and promotional data, medical claims, electronic medical records and social media." See IMS Health Holdings, Inc. Form 10K found at https://www.sec.gov/Archives/edgar/data/1595262/000156459015000673/ims-10k_20141231.htm

[122] DEA Statement on Dispensing Controlled Substances for the Treatment of Pain (2006), p. 5. (https://www.deadiversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm, accessed 5/9/2019).

Figure 5: Comparison of IMS Prescriptions, McCann Baselines, and Ohio Distributions (1997-2018)[123]



113. Another point of reference to evaluate whether shipments into Ohio may be excessive is to look at the shipments in comparison to the APQ that is set annually by DEA, with consideration of FDA's input,[124] to ensure production quantities are sufficient to meet overall U.S. needs.[125] As discussed above, the APQ is determined in part by considering IMS prescription data[126] and also includes factors such as projected medical, scientific, and reserve stock,[127] data on abuse and diversion,[128] and ARCOS data.[129] The value of this

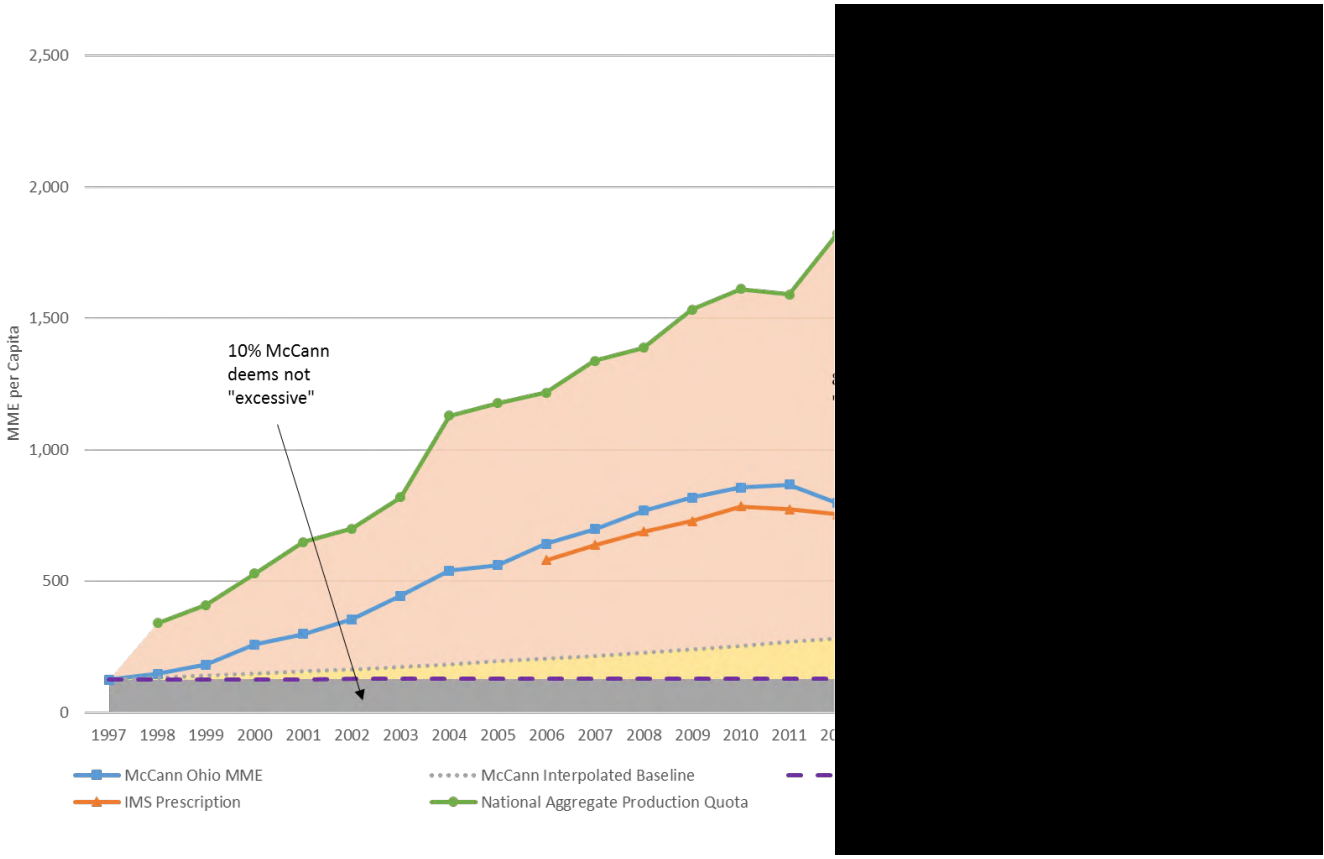
123 McCann Report, Table 44; IMS Data; Census.
124 30(b)(6) Deposition of the Drug Enforcement Administration through the testimony of Stacy Harper-Avilla, April 11, 2019 ("Harper-Avilla Deposition"), 103:23-104:25.
125 Harper-Avilla Deposition, 72:13-18.
126 Harper-Avilla Deposition, 58:17-63:11.
127 Harper-Avilla Deposition, 72:13-18.
128 Harper-Avilla Deposition, 74:7-15.
129 Harper-Avilla Deposition, 67:1-4.

comparison is further supported by DEA's statement that medical need is a significant component of the total APQ.[130]

114. Figure 6 below is identical to Figure 5 with the addition of the APQ (the green dotted line) over the relevant time period. The per capita APQ (measured in MME) is higher than per capita shipments (measured in MME) into Ohio. However, the important comparison is that the shipments into Ohio follow the overall trend of the APQ, illustrating that the shipments into Ohio trend in a similar fashion to the amount of opioid use that the DEA predicted would be necessary to meet overall market needs. In sum, the Ohio shipments per capita closely track with the time periods of recognized nationwide growth and constriction of usage as reflected in the APQ. However, under McCann's methodology, 82% of the APQ would be flagged as excessive.[131]

[130] Rannazzisi Deposition, 92:17-93; 30:12-18.
[131] See Appendix F.

Figure 6: Comparison of National Aggregate Opioid Production Quota, IMS Prescriptions, McCann Baselines, and Ohio Distributions (1997 -2018)[132]



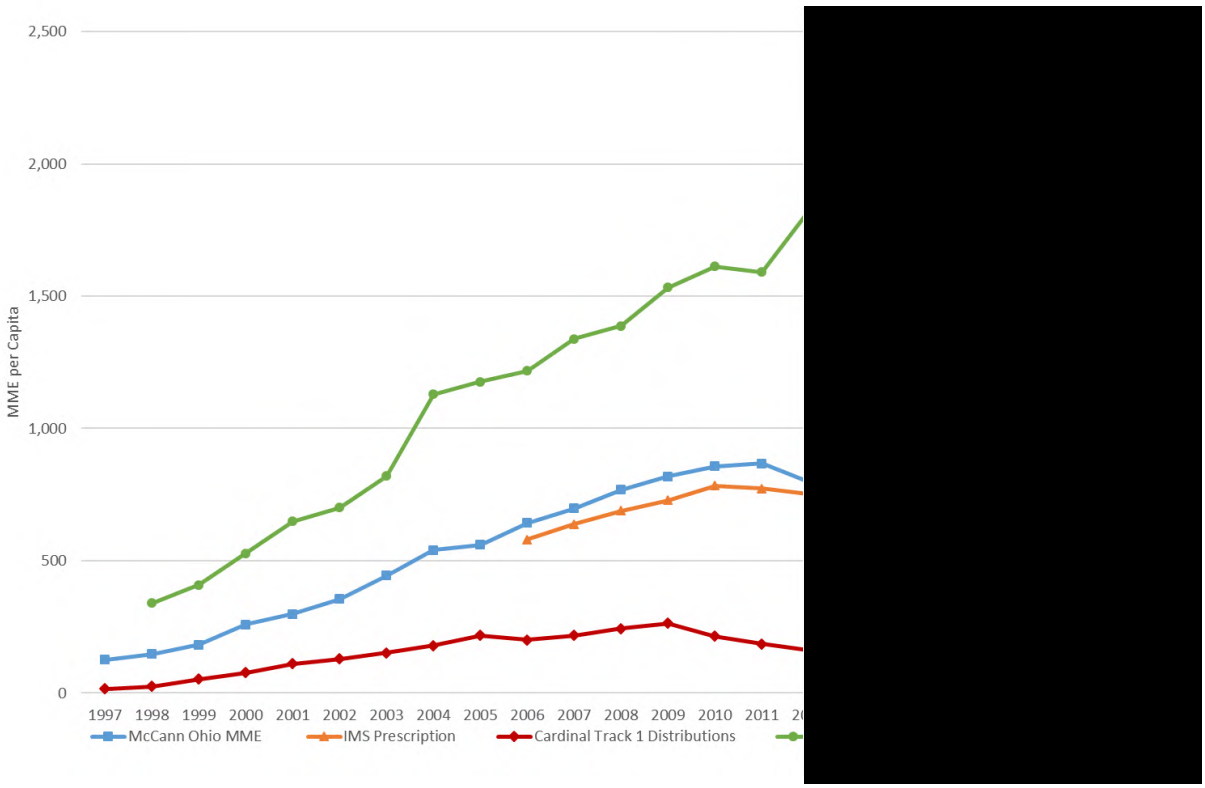
115. Figure 6 also illustrates that the theoretical baseline values constructed by McCann are not consistent with and do not track with the market data for the relevant time period.

[132] DEA Aggregate Production Quota (https://www.deadiversion.usdoj.gov/fed_regs/index.html, accessed 5/9/2019) ("APQ"); McCann Report, Table 44; IMS Data; Census.
The APQ depicted here excludes the 25% buffer instituted from 2013-2016 to establish reserve stocks in the event of a "natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need" (https://www.deadiversion.usdoj.gov/fed_regs/quotas/2013/fr0807.htm, accessed 5/9/2019). The APQ has been converted to MME per capita by dividing by the anhydrous weight factor to convert to salt weight (ARCOS Registrant Handbook, Appendix 3, Conversion Factors for Controlled Substances from Salt to Anhydrous Base or Acid) and multiplying by the MME conversion factor (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Opioid-Morphine-EQ-Conversion-Factors-Aug-2017.pdf, accessed 5/9/2019). See "Calculating Total Daily Dose of Opioids For Safer Dosage" (https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf, accessed 5/9/2019).

C. Cardinal-Specific Shipments

116. With respect to Cardinal-specific shipments per capita, I have modified Figure 6 to include data regarding Cardinal-specific shipments into Cuyahoga and Summit counties. For ease of comparison, the information related to McCann's purported baselines, discussed above, has been removed. The inclusion of the Cardinal-specific data illustrates that when compared to relevant benchmarks of market usage and trends, such as overall Ohio shipments per capita, IMS prescription data, and the DEA-created APQ, the Cardinal-specific shipments appear reasonable and consistent with market trends tied to the use of opioids related to prescriptions issued by licensed prescriber.

Figure 7: Comparison of Cardinal Track 1 Distributions, National Aggregate Production Quota, IMS Prescriptions, and Ohio Distributions (1997 -2018)[133]



117. I performed a similar analysis on a product-specific level to confirm that the results in Figures 5-7 are consistent if the analysis includes only shipments of a single opioid product. The results, found in Appendix E, confirm the shipments of oxycodone and other opioids into Track 1 are at levels that are generally consistent with the overall market trends as reflected by the APQ.

118. In sum, I do not agree with McCann's seemingly random assumptions that led him to conclude that between [redacted] of total MME shipped into Ohio from 1998 to 2017 were possibly unnecessary opioid use. The shipments into Ohio are consistent with third-party data sources related to prescriptions issued by licensed prescribers, and DEA-endorsed indicators. Additionally, the Cardinal-specific shipments are generally in line

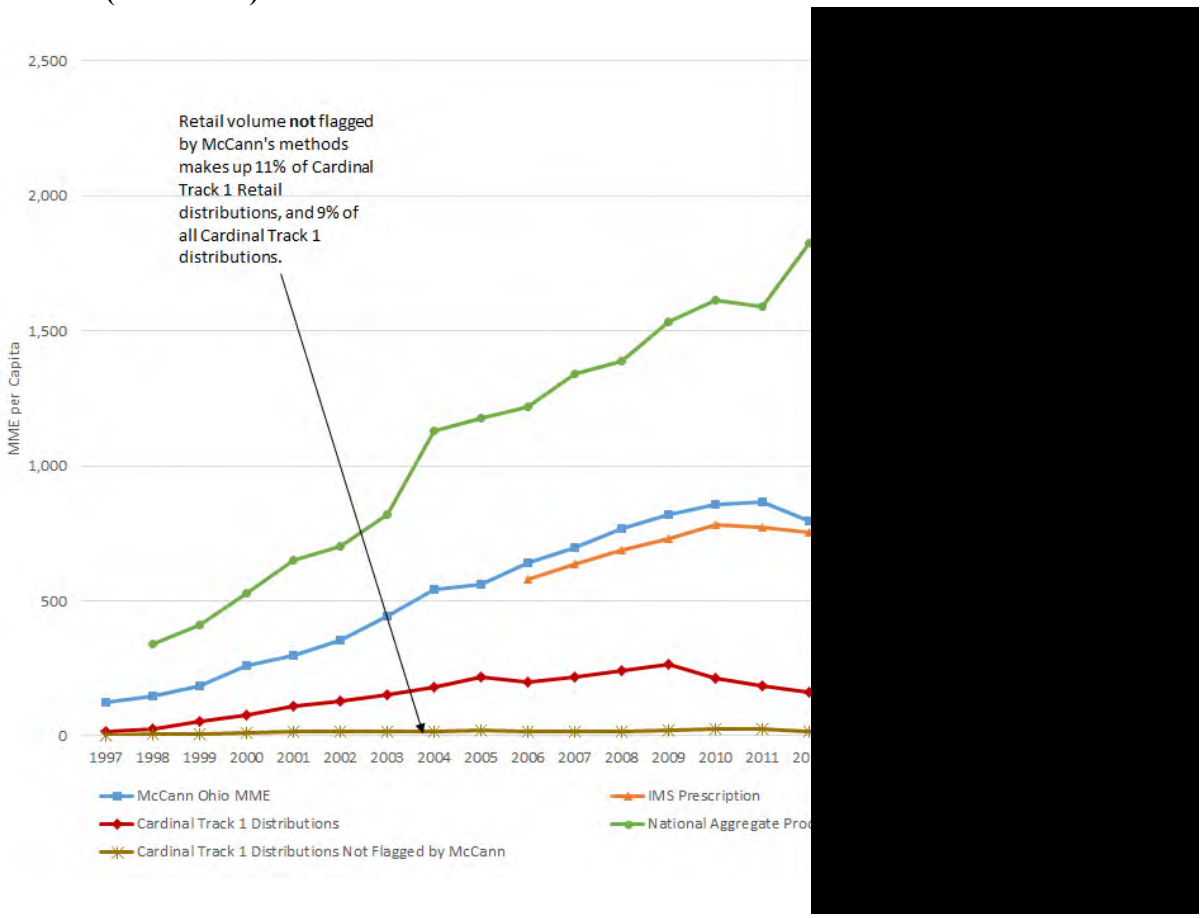
[133] McCann Dataset; McCann Report, Table 44; IMS Data; APQ.

with the shifts in prescribing and the quotas, and Cardinal does not look like an outlier in terms of its share of any of these comparison points.

D. McCann's Conclusions Are Disconnected from Market Reality

119. Fig. 8 (below) is similar to Fig. 7 and includes the Cardinal Track 1 shipments that were not flagged by any of McCann's methods (using MME per capita; represented by brown line). This analysis illustrates that after removal of McCann's flagged shipments, the volume McCann suggests as appropriate is patently insufficient to supply Cardinal's customers with product necessary for the legitimate medical need of their patients. McCann's results are not consistent or applicable to the overall market trend for opioids.

Figure 8: Comparison of Cardinal Track 1 Opioid Distributions, Cardinal Track 1 Distributions Not Flagged by McCann, National Aggregate Production Quota, IMS Prescriptions, and Ohio Distributions (1997 -2018)[134]



[134] McCann Dataset; McCann Report, Table 44; IMS Data; APQ.

VIII. RAFALSKI SCHEDULE III RELATED TO CARDINAL'S SUSPICIOUS ORDER MONITORING IS INACCURATE

120. Rafalski reports that from 1/1/13 to present, Cardinal identified [redacted] suspicious orders for Summit and Cuyahoga counties. He purports to have examined those [redacted] orders to determine whether Cardinal made any additional shipments of the same base code/drug family[135] to the same customer after a suspicious order was identified - but before the end of its monthly order accrual cycle ("accrual cycle") with a lack of documented due diligence. Rafalski concludes that there were [redacted] improper shipments of the same opioid base code to a customer after a suspicious order and during the same order accrual cycle.

121. Rafalski describes Cardinal's system as "designed so that if a customer exceeded a threshold and had a suspicious order reported based on that breach Cardinal Health was not to ship any more of that base code/drug code to that customer until the threshold reset at the end of the accrual cycle or there was adequate due diligence done to clear the order and subsequent orders."[136]

122. I have not performed a detailed review of, nor am I opining on, Cardinal's anti-diversion program in general. However, I reviewed the logic Rafalski used to conclude that each of the [redacted] shipments was improperly shipped and reviewed the underlying data related to the shipments. I disagree with Rafalski's characterization of those [redacted] shipments; to the contrary, my analysis indicates that all [redacted] appear to have been shipped in a manner consistent with the customer's accrual cycle. The reasons for Rafalski's incorrect conclusions can be grouped into at least four categories.

123. First, Rafalski improperly assumes that the accrual cycle for all of the customers reviewed began on the 22nd day of the month.[137] [redacted]

[135] A base code or drug code is identified by the first four characters of the drug code that corresponds to the portion of the controlled substance molecule identified as the "base" drug.
[136] Rafalski Report, pages 67-68
[137] Rafalski Report, Schedule III ("Shipped more after SOR (on or before 21st").
[138] Cameron Deposition, 176:9-18.

[redacted]

124. Second, Rafalski uses each shipment's invoice date to determine whether the order was placed within the same monthly accrual cycle as the suspicious order. [redacted]

125. Third, Rafalski fails to review the applicable product ordering threshold that is in place at the end of the customer's accrual cycle. Sometimes this change occurred in the middle of an accrual cycle.[140] Per Todd Cameron, "[o]ne thing that happens, when we change a threshold during the month, every subsequent order that goes over what the amount was prior to the change until the next accrual cycle reset looks like a released order."[141] Rafalski's failure to account for threshold changes leads to the improper inclusion of shipments that were below the customer's monthly threshold.

126. Finally, Rafalski erroneously flags shipments that were subsequent to a suspicious order even if that shipment was for an amount under the customer's threshold for the accrual cycle.[142] The data indicates that Cardinal had a monthly threshold limit in dosage units for each customer by base code/drug family. If an order is held and not shipped, a subsequent smaller order that is under the monthly threshold may be shipped. By failing to account for these occurrences, Rafalski improperly identifies shipments that did not violate a customer's monthly threshold limit.

127. For example, Rafalski identified as improper two Discount Drug Mart #33 (BD1354149) shipments that occurred after suspicious orders of hydrocodone. The two suspicious orders

139 Ibid.
140 Cameron Deposition, 214:23-215:21.
141 Cameron Deposition, 215:17-21.
142 CAH_MDL280400619126.

were placed on 5/6/2015 and total of [redacted] dosage units. The maximum amount of hydrocodone Discount Drug Mart had previously ordered in a day was [redacted] dosage units. After Cardinal held and reported the order, Discount Drug Mart received a shipment for [redacted] dosage units a few days later – an amount that is much more similar to its recent shipments. Without knowing the circumstances of this particular shipment, and even without specific expertise with Cardinal's anti-diversion program, it appears clear to me that the suspicious order may have been an error. In identifying the subsequent shipment as improper, Rafalski appears to have dismissed the possibility that Cardinal stopped an order of "unusual size" that was potentially placed in error, and shipped an order of "usual size."

128. In summary, Rafalski appears to have grossly misinterpreted the data related to Cardinal's suspicious orders. Rafalski provides little detail in his report or supporting materials regarding the data he evaluated, how he conducted his analysis, and the underlying bases for his assumptions and conclusions. Therefore, I reserve the right to supplement my analyses related to these shipments.

IX. CONCLUSION

129. In my opinion, Plaintiffs' expert Craig McCann has not performed a reasonable or reliable analysis to identify Cardinal shipments of unusual size, pattern, or frequency.

130. McCann does not identify a single instance of diversion related to an opioid product shipment by Cardinal, much less an instance of diversion related to an order that Cardinal should have stopped but failed to do so. Further, he does not even attempt to identify a causal link between his data analysis and instances of product diversion.

131. Shipments by Cardinal to Cuyahoga and Summit county customers were proportional to, and reasonably consistent with, trends in national physician prescribing and the DEA aggregate production quotas for the time period analyzed.

132. McCann fails to take into account the distributor's role in the supply chain, including but not limited to, fulfillment of medical demand for opioids by pharmacies based on prescriptions from doctors to meet legitimate patient medical needs.

133. McCann's overly-simplistic methods would flag an excessive number of transactions related to almost any product or activity that exhibits growth or fluctuation. His methods are "blunt instruments" that systematically flag large numbers of transactions without any regard for the complexity or nuances in the underlying data.

134. McCann's carry-forward assumption accounts for 94% of the dosage units flagged for unusual size in his six-month trailing method. However, the carry-forward assumption is not supported by any regulation, statute, Cardinal's actual anti-diversion program or SOM policies, nor any other real world requirement or system.

135. McCann fails to properly take into account any market-based or customer-specific contextual elements that affected opioid shipments to Cardinal customers, such as changes in opioid prescribing patterns, changed fulfillment strategies (e.g., hydrocodone rescheduling), pharmacy customer store size, pharmacy location, or other factors that could affect legitimate customer demand for opioids, or other customer-specific factors that the DEA acknowledges are important to identify orders of unusual size, pattern, or frequency.

136. McCann stated in his deposition that he did not assess the meaning of the data used in his analysis, which explains why he produced unreliable results. Plaintiffs' experts Rafalski, Cutler, and McGuire all endorse or rely upon McCann's analysis to draw conclusions in their reports without doing anything to correct McCann's errors.

137. McCann's methods, endorsed or relied upon by other Plaintiffs' experts (Rafalski, McGuire, and Cutler), are deficient because they do not account for customer-specific factors that the DEA has suggested Cardinal and other registrants take into account, and they result in the identification of more than [redacted] shipments as "suspicious," a result that does not hold up under further scrutiny. My analysis indicates that over 99% of the shipments identified by McCann are affected by one or more contextual factors that should be taken into account before declaring that an order is of unusual size.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 10, 2019.

John J. MacDonald III

APPENDIX A: SUMMARY OF MCCANN'S ANALYSES

Table 14: McCann Methodologies and Cardinal Percentage Flagged by Drug (2006-2017)[143]

	% Dosage Units Flagged					
Drug Code	Six-Month Trailing	Two Times Trailing Twelve-Month	Three Times Twelve-Month Trailing	8,000 Monthly Maximum	Maximum Daily Dosage	Any Method
HYDROCODONE	[redacted]					
OXYCODONE						
CODEINE						
MORPHINE						
HYDROMORPHONE						
OXYMORPHONE						
TAPENTADOL						
FENTANYL						
MEPERIDINE						
OPIUM, POWDERED						
LEVORPHANOL						
DIHYDROCODEINE						

[143] McCann Dataset.

Table 15: Percentage of McCann Flagged Cardinal Dosage Units Affected by Contextual Analysis

Contextual Analysis	% of McCann's Six-Month Trailing Method Dosage Units	% of McCann's Twice Trailing Method Dosage Units	% of McCann's Three Times Trailing Method Dosage Units	% of McCann's 8,000 Monthly Maximum Method Dosage Units	% of McCann's Maximum Daily Dosage Units	% of Any McCann Method Dosage Units
Shipments captured by McCann "carry-forward" rule	94.3%	72.6%	78.3%	57.8%	37.4%	31.8%
Hydrocodone Rescheduling	5.0%	8.8%	14.1%	0.0%	0.0%	19.2%
Size of Pharmacy	84.0%	83.6%	81.1%	80.3%	82.2%	82.3%
Proximity to a Hospital	26.9%	28.8%	31.6%	27.6%	28.1%	28.3%
Hospital Contractual Relationship	8.6%	7.5%	7.2%	8.7%	8.6%	8.4%
Total % of McCann's Analysis Affected by Contextual Analysis	**99.6%**	**97.9%**	**98.0%**	**96.9%**	**95.6%**	**95.5%**

APPENDIX B: MCCANN'S METHODOLOGIES APPLIED TO 10 TOP NON-CONTROLLED SUBSTANCES

Table 16: McCann's Methods Applied to Cardinal 10 Top Non-Controlled Substances (2006-2017)[144]

Ingredient Name	Description	% Flagged - Six-Month Trailing	% Flagged - Two Times Trailing Twelve-Month	% Flagged - Three Times Trailing Twelve-Month	% Flagged - 8,000 Maximum Monthly
Oxycodone	Opioid	[redacted]			
Hydrocodone	Opioid				
Levothyroxine	Thyroid Medication, e.g. Synthroid, Tirosint	98.6%	92.2%	82.9%	45.7%
Metoprolol	High Blood Pressure Medication, Beta-Blocker, e.g. Lopressor	97.7%	85.9%	75.2%	55.4%
Lisinopril	High Blood Pressure Medication, ACE inhibitor, e.g. Prinivil, Qbrelis	97.8%	93.4%	87.8%	81.7%
Metformin	Anti-Diabetic Medication, e.g. Glucophage, Glumetza	99.8%	91.7%	84.9%	81.3%
Polyethylene Glycol 3350	Laxative, e.g. Miralax	92.3%	89.8%	73.7%	46.3%
Atorvastatin	High Cholesterol Medication, e.g. Lipitor	88.9%	86.4%	75.8%	27.4%
Hydrochlorothiazide	High Blood Pressure / Fluid Retention Medication, e.g. Microzide	96.1%	94.2%	83.3%	59.4%
Atenolol	High Blood Pressure Medication, Beta-Blocker, e.g. Tenormin	96.1%	91.3%	82.0%	58.0%
Furosemide	Diuretic, e.g. Lasix	94.9%	87.7%	78.0%	49.0%
Cetirizine	Allergy Medication, e.g. Zyrtec	93.8%	91.6%	78.2%	67.3%

138. One of the 10 non-controlled products I analyzed is metoprolol, a commonly prescribed beta-blocker that treats high blood pressure, angina, and heart failure. In addition to 97.7% of shipments being flagged, it is interesting to note that metoprolol has a distribution trend very similar to a product McCann did analyze, hydrocodone, and metoprolol would be flagged by McCann's method in a similar manner. The similarity in distribution patterns between metoprolol and hydrocodone is one more indicator that the shipments flagged are not suspicious orders with respect to size, pattern, or frequency – there is likely something else going on with respect to the ordering patterns.

139. I have analyzed the relationship between Cardinal's distributions of hydrocodone and of metoprolol. Cardinal distributions of hydrocodone and metoprolol are highly correlated, with an R-squared of 0.8557.

[144] Cardinal Non-Opioid Distribution Data; McCann Dataset; Elsevier Database. Includes pharmacy customers who purchase opioids in the period. I have not replicated the maximum daily dosage units on non-controlled substances as it is not applicable to those products.

Figure 9: Regression of Hydrocodone on Metoprolol Dosage Units Shipped by Cardinal to Pharmacies (2006-September 2014)[145]

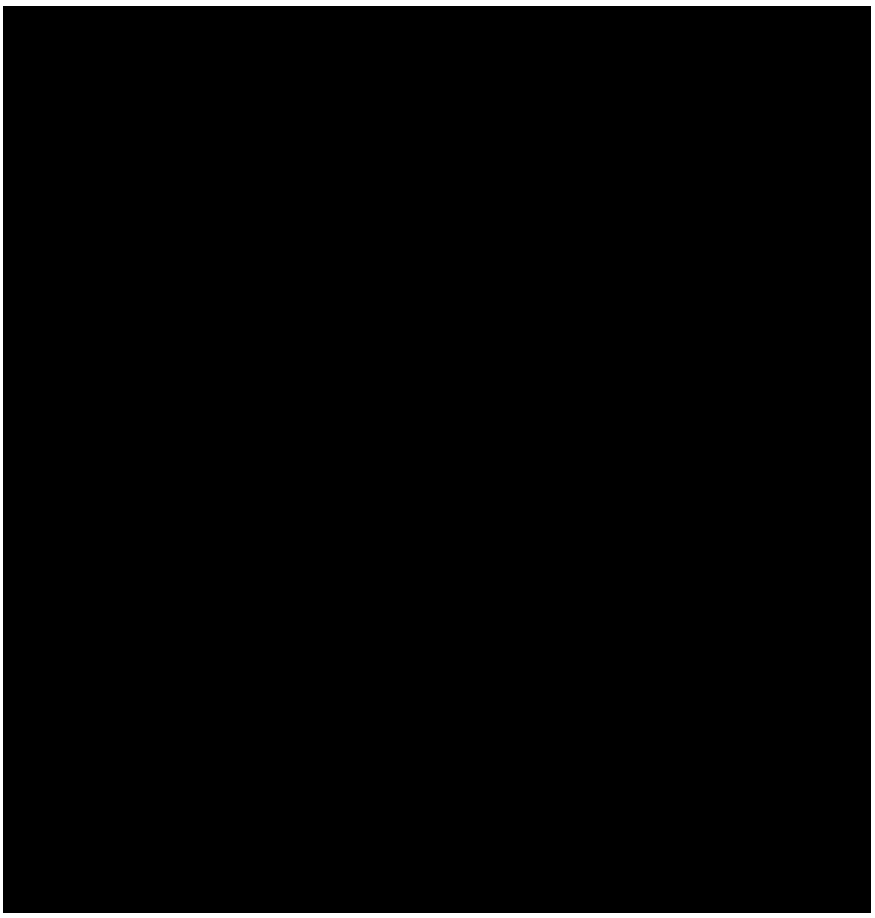


Table 17: List of Cardinal 10 Top Non-Controlled Substances

Attached as a separate file.

[145] Cardinal Non-Opioid Distribution Data; McCann Dataset; Elsevier Database. This analysis is limited to 2006-September 2014 to so that the comparison is not impacted by the hydrocodone rescheduling in October 2014, which corresponds to an increase of hydrocodone distributions by Cardinal when it became the primary distributor of hydrocodone for pharmacies such as CVS and Discount Drug Mart. Includes pharmacy customers who purchased both hydrocodone and metoprolol in the period.

APPENDIX C: ANALYSIS OF CONTROLLED SUBSTANCE PERCENTAGES

Table 18: Controlled Substance and Opioid Concentration to Track 1 Cardinal Customers[146]

Customer(s)	Controlled Substance %	Opioid %	Six-Month Trailing % Flagged	Two Times Trailing % Flagged	Three Times Trailing % Flagged	Maximum Monthly %	Maximum Daily % Flagged	Any Method % Flagged
McCann Customers								
CVS								
CVS #3322								
CVS #4800								
CVS #4347								
CVS #3035								
CVS #3360								
CVS #4300								
CVS #3338								
All Other Customers								

Table 19: Strata Analysis of Flagged Cardinal CVS Stores (2006-2017)[147]

Total Volume Percentile Buckets	Controlled Substance %	Opioid %	Six-Month Trailing % Flagged	Two Times Trailing % Flagged	Three Times Trailing % Flagged	Maximum Monthly %	Maximum Daily % Flagged	Any McCann Method %
Small Volume CVS Stores								
Medium Volume CVS Stores								
Large Volume CVS Stores								
Overall								

[146] McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS_MDLT1_000124148-000124180 ("CVS Distribution Data").

[147] McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS Distribution Data.

CVS small, medium, and large customers have been categorized based on total distributions between the 0-25th, 25th-75th, and above the 75th percentiles, respectively.

Table 20: CS % for All Track 1 Cardinal CVS Pharmacies Over Time (2006-2017)[148]

Customer Name	Customer DEA Number(s)	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Overall
CVS #3322	AR7531418	17.3%	18.3%	21.2%	21.6%	22.1%	22.3%	22.4%						
CVS #4347	AR1404730	12.7%	13.9%	15.7%	14.5%	14.0%	15.0%	14.8%						
CVS #3035	AR6686301	13.9%	15.3%	16.6%	15.6%	15.5%	17.2%	17.5%						
CVS #4300	AR6448888	11.4%	12.1%	13.2%	13.1%	12.4%	13.2%	14.1%						
CVS #4800	BR0287234	18.5%	19.6%	20.2%	21.6%	21.3%	20.7%	19.1%						
CVS #3360	AR2879318	14.2%	15.3%	16.8%	16.1%	16.3%	17.6%	17.3%						
CVS #3338	AR7883449	10.5%	11.5%	13.5%	11.8%	10.2%	11.7%	12.3%						
CVS #3329	AR2879217	10.8%	11.6%	13.2%	13.2%	14.0%	14.6%	15.0%						
CVS #3301	AR2953568	10.1%	10.1%	12.4%	11.7%	12.2%	12.7%	12.0%						
CVS #3339	AR9581415	13.0%	13.6%	15.6%	15.9%	15.8%	16.0%	15.6%						
CVS #3634	BR4293988	7.7%	8.2%	8.5%	8.5%	8.6%	9.2%	9.4%						
CVS #4359	AR2151051	11.3%	12.3%	12.6%	12.4%	10.9%	11.7%	11.4%						
CVS #4345	AR8147818	9.9%	9.5%	10.3%	10.4%	10.6%	10.6%	10.8%						
CVS #3333	AR8556663	14.3%	15.8%	16.4%	16.8%	15.1%	15.8%	15.9%						
CVS #4803	BR3522009	8.1%	9.1%	11.2%	12.5%	13.3%	11.4%	10.8%						
CVS #3306	AR2960688	14.3%	14.5%	15.4%	14.8%	13.5%	12.9%	13.8%						
CVS #4499	BR5638880	10.7%	10.7%	11.3%	11.2%	11.4%	12.3%	12.6%						
CVS #4350	AR9079826	7.9%	7.8%	8.3%	9.2%	9.6%	10.6%	11.0%						
CVS #3817	BR3832335	13.2%	13.1%	13.5%	13.6%	12.3%	12.6%	12.5%						
CVS #4437	BR5144403	10.0%	10.8%	11.8%	10.7%	10.0%	10.8%	10.7%						
CVS #3355	AR2916659	17.6%	17.9%	20.0%	19.1%	19.4%	17.8%	18.6%						
CVS #3346	AR2877136	7.4%	8.3%	9.2%	9.7%	9.5%	9.8%	8.6%						
CVS #3359	AR2916798	10.4%	11.2%	12.3%	11.5%	11.0%	12.1%	11.9%						
CVS #7371	BR3920089	8.3%	9.2%	8.9%	9.7%	10.5%	9.8%	9.7%						
CVS #4333	AR7850933	16.2%	16.8%	17.6%	17.3%	16.4%	18.3%	17.6%						
CVS #3320	AR4858087	16.8%	18.3%	19.7%	17.3%	16.7%	16.8%	17.2%						
CVS #3332	AR5438660	11.0%	11.9%	13.5%	12.5%	13.8%	13.5%	13.7%						
CVS #3041	AR2943656	16.5%	18.4%	19.1%	19.4%	19.2%	19.5%	18.5%						
CVS #3343	AR9730323	9.4%	9.7%	10.9%	11.7%	12.3%	12.2%	12.5%						
CVS #4312	AR6492223	19.9%	21.3%	23.1%	20.7%	21.1%	20.8%	19.2%						
CVS #4301	AR6779904	11.1%	12.9%	14.2%	14.2%	13.9%	15.6%	14.4%						
CVS #3032	AR2943163	7.5%	8.1%	8.9%	8.1%	9.0%	8.5%	9.4%						
CVS #4320	AR6828543	10.8%	11.7%	12.3%	12.7%	14.0%	14.9%	14.3%						
CVS #3645	BR4293990	10.1%	10.2%	10.9%	10.9%	10.3%	10.7%	10.2%						
CVS #3028	AR2939506	12.8%	14.0%	15.1%	15.2%	14.7%	15.4%	16.2%						
CVS #3314	AR9205382	12.8%	14.5%	15.4%	15.9%	14.5%	15.2%	15.0%						
CVS #4054	BR3832347	11.1%	10.9%	11.7%	11.5%	11.6%	12.4%	13.7%						
CVS #7370	BR3920077	9.6%	10.2%	10.9%	10.3%	10.4%	11.5%	10.9%						
CVS #4304	AR6450251	10.3%	10.8%	12.4%	12.2%	11.5%	12.3%	12.8%						
CVS #3092	FO1803407, BC5772632	12.0%	12.7%	13.2%	13.9%	14.0%	14.4%	14.1%						
CVS #3334	AR2876778	11.1%	10.9%	11.7%	11.1%	11.4%	12.7%	13.1%						
CVS #3337	AR2880311	6.3%	6.9%	6.9%	6.1%	6.3%	6.9%	6.6%						
CVS #4336	AR8225131	13.6%	14.6%	16.9%	16.1%	17.4%	17.6%	17.1%						
CVS #4338	AR7855779	13.8%	14.9%	16.8%	18.8%	19.0%	19.9%	18.6%						
CVS #4316	AR6828531	13.9%	14.4%	15.5%	15.1%	15.3%	16.1%	15.8%						
CVS #4330	AR8116801	10.3%	12.1%	11.8%	12.5%	12.8%	13.7%	12.6%						
CVS #4101	BR3926372	8.8%	9.2%	9.7%	9.4%	10.2%	10.5%	10.9%						
CVS #4607	BR3920053	10.9%	11.3%	11.9%	11.0%	9.8%	12.1%	11.5%						
CVS #5366	BR5648893	7.6%	7.6%	8.9%	7.6%	8.3%	8.1%	8.1%						
CVS #4309	AR6270134	16.7%	17.9%	19.2%	18.3%	19.0%	19.4%	19.4%						
CVS #4034	BR3832309	10.8%	11.1%	12.1%	11.4%	11.4%	12.3%	11.8%						
CVS #3347	AR2887531	6.5%	8.5%	10.0%	8.9%	8.8%	10.1%	9.1%						
CVS #3083	FO1803368, BC5772579	18.7%	20.5%	21.6%	22.4%	23.3%	25.7%	25.3%						
CVS #2469	FO1802950, BC6576764	10.9%	10.5%	11.2%	11.3%	11.1%	11.4%	10.6%						
CVS #3340	AR2876944	14.2%	16.3%	16.8%	16.1%	15.4%	14.7%	14.2%						
CVS #2587	FO1803267, BC7023865	13.0%	12.2%	15.2%	15.0%	14.6%	14.1%	13.6%						
CVS #2503	FO1802998, BC6668997	13.6%	13.8%	13.7%	13.8%	14.4%	16.1%	16.2%						
CVS #3697	BR4169896	8.5%	9.2%	10.2%	9.8%	9.6%	10.3%	9.2%						
CVS #4282	BR3901217	11.5%	10.8%	12.8%	12.0%	13.4%	13.7%	13.7%						
CVS #7687	BR5209172	8.7%	9.0%	10.0%	9.9%	9.8%	9.2%	10.7%						
CVS #4572	FO1616311				21.5%	15.0%	17.2%	17.1%						
CVS #4811	BR3137014	9.5%	10.1%	11.3%	10.3%	10.9%	12.4%	14.3%						
CVS #4488	BR5347768	15.5%	16.3%	16.3%	15.8%	15.9%	16.2%	16.7%						
CVS #4208	BR3971682	10.5%	9.7%	11.5%	11.4%	10.7%	10.0%	10.5%						
CVS #4305	AR9102651	8.1%	8.3%	9.2%	10.1%	9.9%	9.1%	9.9%						
CVS #4402	BR3298470	10.9%	10.8%	12.6%	12.2%	12.7%	12.6%	12.4%						
CVS #8932	FO2216794					12.3%	12.8%	11.1%						
CVS 10893	FO7114666													
CVS 17340	FO5704766													
CVS 17411	FO5704780													
CVS 16927	FO5704475													
CVS 16245	FO5713878													
CVS 16381	FO5704057													
CVS 17305	FO5704730													
CVS 16246	FO5703992													
CVS 16665	FO5704336													
CVS 17303	FO5704716													
CVS 17109	FO5704576													
CVS 16380	FO5704045													
CVS 16962	FO5704499													
CVS 16382	FO5704083													
CVS #4106	BR3971670													

[148] McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS Distribution Data.

Table 21: Opioid % for All Track 1 Cardinal CVS Pharmacies Over Time (2006-2017)[149]

Customer Name	Customer DEA Number(s)	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Overall
CVS #3322	AR7531418	8.7%	9.5%	11.3%	11.9%	12.6%	12.6%	12.1%						
CVS #4347	AR1404730	5.9%	6.6%	7.8%	7.4%	7.4%	7.7%	7.2%						
CVS #3035	AR6686301	6.3%	7.5%	8.0%	7.5%	7.5%	7.9%	7.7%						
CVS #4300	AR6448888	4.7%	5.1%	5.8%	6.0%	5.6%	5.9%	5.8%						
CVS #4800	BR0287234	10.4%	11.2%	12.2%	13.7%	13.5%	12.7%	11.3%						
CVS #3360	AR2879318	6.3%	7.3%	7.7%	7.2%	7.4%	7.8%	7.3%						
CVS #3338	AR7883449	4.4%	5.2%	6.5%	5.9%	4.8%	5.5%	5.7%						
CVS #3329	AR2879217	3.7%	4.1%	4.8%	4.7%	5.1%	5.8%	5.6%						
CVS #3301	AR2953568	3.3%	3.9%	4.5%	4.7%	4.4%	4.4%	3.6%						
CVS #3339	AR9581415	5.1%	5.9%	6.5%	7.0%	6.9%	7.3%	6.8%						
CVS #3634	BR4293988	2.2%	2.8%	3.0%	3.2%	3.3%	3.4%	3.3%						
CVS #4359	AR2151051	4.0%	4.6%	4.3%	4.0%	3.4%	3.4%	3.4%						
CVS #4345	AR8147818	3.0%	3.4%	3.5%	3.8%	3.6%	3.5%	3.3%						
CVS #3333	AR8556663	6.8%	8.2%	8.5%	8.6%	8.2%	8.0%	7.3%						
CVS #4803	BR3522009	3.9%	5.0%	6.8%	8.4%	8.5%	7.1%	5.9%						
CVS #3306	AR2960688	6.3%	6.4%	6.9%	6.3%	6.0%	5.7%	5.8%						
CVS #4499	BR5638880	4.0%	4.0%	4.5%	4.7%	4.7%	4.9%	5.0%						
CVS #4350	AR9079826	3.1%	3.4%	3.0%	4.1%	4.5%	5.0%	4.6%						
CVS #3817	BR3832335	6.2%	6.1%	6.2%	6.3%	5.5%	5.6%	5.4%						
CVS #4437	BR5144403	4.2%	4.6%	5.1%	4.4%	4.2%	4.4%	4.1%						
CVS #3355	AR2916659	8.2%	8.4%	9.1%	8.7%	9.5%	8.5%	8.4%						
CVS #3346	AR2877136	2.4%	3.1%	3.8%	4.3%	4.6%	4.6%	3.6%						
CVS #3359	AR2916798	3.8%	4.2%	5.0%	4.8%	4.4%	4.9%	4.3%						
CVS #7371	BR3920089	3.5%	4.1%	4.2%	4.9%	5.7%	5.0%	4.4%						
CVS #4333	AR7850933	7.9%	8.0%	8.8%	8.4%	7.9%	8.1%	7.4%						
CVS #3320	AR4858087	8.1%	8.7%	9.4%	8.1%	7.9%	8.1%	8.0%						
CVS #3332	AR5438660	4.5%	4.9%	5.7%	5.4%	5.8%	5.9%	5.6%						
CVS #3041	AR2943656	8.1%	9.5%	10.1%	10.5%	10.8%	11.1%	10.0%						
CVS #3343	AR9730323	3.4%	3.7%	4.4%	5.0%	5.4%	5.0%	5.2%						
CVS #4312	AR6492223	9.9%	11.4%	11.9%	10.7%	10.8%	10.1%	8.9%						
CVS #4301	AR6779904	4.9%	6.3%	6.3%	5.9%	5.9%	6.6%	5.7%						
CVS #3032	AR2943163	2.4%	2.8%	3.2%	3.3%	3.5%	3.6%	3.7%						
CVS #4320	AR6828543	4.3%	5.2%	5.6%	6.4%	7.4%	7.7%	6.8%						
CVS #3645	BR4293990	4.6%	4.3%	4.5%	4.8%	4.3%	4.3%	3.9%						
CVS #3028	AR2939506	6.3%	7.0%	7.7%	7.8%	7.4%	7.2%	7.5%						
CVS #3314	AR9205382	5.9%	7.1%	7.4%	7.7%	7.3%	7.4%	6.7%						
CVS #4054	BR3832347	5.1%	5.3%	5.2%	5.4%	5.5%	5.8%	5.9%						
CVS #7370	BR3920077	3.7%	4.2%	4.3%	4.0%	4.3%	5.1%	3.8%						
CVS #4304	AR6450251	3.6%	3.4%	3.8%	4.1%	3.7%	4.1%	3.9%						
CVS #3092	FO1803407, BC5772632	4.5%	5.2%	5.2%	5.8%	5.7%	5.9%	5.9%						
CVS #3334	AR2876778	4.3%	4.5%	4.7%	4.9%	4.8%	5.4%	5.3%						
CVS #3337	AR2880311	2.3%	2.5%	2.6%	2.3%	2.7%	2.9%	2.3%						
CVS #4336	AR8225131	6.3%	6.6%	7.9%	7.9%	8.7%	8.9%	8.1%						
CVS #4338	AR7855779	6.4%	7.4%	8.7%	9.6%	10.5%	11.0%	9.1%						
CVS #4316	AR6828531	6.1%	7.0%	7.9%	8.3%	8.6%	8.7%	8.1%						
CVS #4330	AR8116801	4.9%	6.4%	6.4%	6.9%	7.0%	7.8%	6.2%						
CVS #4101	BR3926372	2.7%	2.9%	3.4%	3.2%	3.4%	3.8%	3.6%						
CVS #4607	BR3920053	3.9%	4.4%	5.3%	4.8%	4.1%	5.3%	4.4%						
CVS #5366	BR5648893	3.0%	3.0%	4.5%	3.8%	4.7%	4.3%	3.6%						
CVS #4309	AR6270134	8.4%	9.5%	10.3%	9.7%	9.7%	9.4%	9.1%						
CVS #4034	BR3832309	4.0%	4.0%	4.4%	4.4%	4.3%	4.9%	4.4%						
CVS #3347	AR2887531	1.8%	3.0%	4.0%	3.5%	3.7%	3.6%	3.3%						
CVS #3083	FO1803368, BC5772579	8.6%	10.3%	11.4%	11.3%	12.8%	14.5%	13.6%						
CVS #2469	FO1802950, BC6576764	4.0%	3.7%	3.4%	3.5%	3.3%	3.4%	2.7%						
CVS #3340	AR2876944	5.3%	6.5%	6.4%	6.1%	6.2%	5.5%	5.2%						
CVS #2587	FO1803267, BC7023865	5.2%	4.8%	6.2%	6.2%	5.7%	5.9%	5.4%						
CVS #2503	FO1802998, BC6668997	5.3%	6.3%	6.3%	6.2%	7.0%	7.2%	6.8%						
CVS #3697	BR4169896	2.6%	2.7%	2.8%	2.9%	2.6%	2.9%	2.2%						
CVS #4282	BR3901217	4.9%	5.1%	6.6%	6.3%	7.6%	7.4%	6.9%						
CVS #7687	BR5209172	2.1%	2.4%	2.6%	2.5%	2.3%	2.3%	2.8%						
CVS #4572	FO1616311				12.5%	6.7%	7.6%	7.1%						
CVS #4811	BR3137014	3.6%	4.2%	5.1%	4.7%	4.9%	5.6%	5.8%						
CVS #4488	BR5347768	6.3%	7.7%	7.5%	6.7%	7.2%	7.4%	7.2%						
CVS #4208	BR3971682	3.6%	3.6%	4.0%	4.2%	4.5%	4.0%	3.7%						
CVS #4305	AR9102651	3.2%	3.2%	3.9%	4.9%	5.0%	3.4%	3.0%						
CVS #4402	BR3298470	4.7%	5.0%	6.6%	6.9%	7.4%	6.7%	5.5%						
CVS #8932	FO2216794					4.3%	4.8%	3.4%						
CVS 10893	FO7114666													
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CVS 17305	FO5704730													
CVS 16246	FO5703992													
CVS 16665	FO5704336													
CVS 17303	FO5704716													
CVS 17109	FO5704576													
CVS 16380	FO5704045													
CVS 16962	FO5704499													
CVS 16382	FO5704083													
CVS #4106	BR3971670													

[149] McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS Distribution Data.

APPENDIX D: CONSIDER PROXIMITY TO A HOSPITAL

140. I have expanded my analysis found in Table 11 to include pharmacies located within 0.5 miles of a hospital (not just 0.25 miles).

Table 22: Percentage of McCann Flagged Cardinal Dosage Units Within Close Proximity to Hospital (0.5 Miles) (2006-2017)[150]

McCann Method	% of McCann Flagged Dosage Units Affected
Six-Month Trailing	38.3%
Two Times Trailing Twelve-Month	40.0%
Three Times Trailing Twelve-Month	41.9%
8,000 Monthly Maximum	39.4%
Maximum Daily Dosage Units	39.2%
Any McCann Method	*39.4%*

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[150] McCann Dataset; ARCOS; Texas A&M University GeoInnovation Center; TAMU GeoServices. Available at https://geoservices.tamu.edu/ (Accessed 5/8/2019). Close Proximity to a Hospital has been defined as on-site at hospital, within 0.50 miles of a hospital, or be the nearest pharmacy to a hospital.

APPENDIX E: CARDINAL TRACK 1 SHIPMENTS COMPARED TO THE APQ

141. In addition to the analysis found in Figure 7, I have confirmed in Table 23 that the Cardinal shipments of each opioid into Track 1 are at levels that remain consistent with the overall market trends as reflected by the APQ.

Table 23: Cardinal Track 1 Distributions in Grams per Capita as a Percentage of the National Aggregate Production Quota (2006 – 2017)[151]

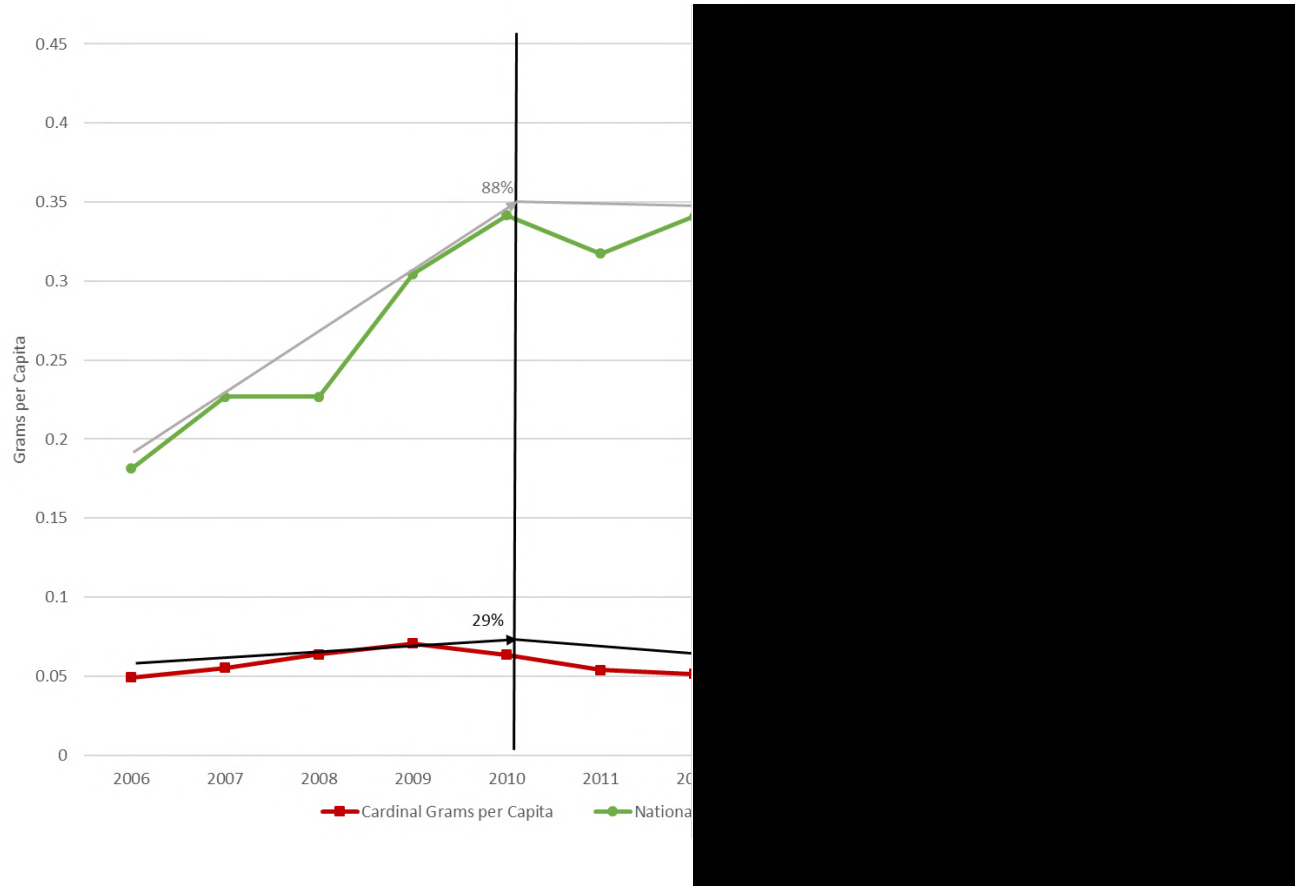
	Cardinal Track 1 Distributions in Grams per Capita - Percentage of Quota without Buffer	
Drug Name	**2006 - 2010**	**2011 - 2017**
Oxycodone	23.6%	[redacted]
Hydrocodone	4.9%	
Morphine	22.4%	
Codeine	5.8%	
Tapentadol		
Meperidine	21.1%	
Hydromorphone	17.6%	
Oxymorphone	31.9%	
Fentanyl	13.0%	
Dihydrocodeine	1.4%	
Opium		
Levorphanol	4.0%	

142. I have also analyzed the growth of Cardinal's Track 1 oxycodone shipments and compared them to the growth of the oxycodone APQ. As demonstrated in Figure 10, Cardinal's Track 1 shipments are growing at a rate that is markedly lower than the rate at which oxycodone APQ is growing.[152]

[151] McCann Data; APQ.

[152] In addition to completing this analysis for oxycodone, I have confirmed that it yields similar results for each of the other 11 opioids. Additionally, I have expanded this analysis to include only customers that are active across the period, and have found no material difference in the results of the analysis.

Figure 10: Cardinal Track 1 Distributions and National Aggregate Production Quotas: Oxycodone (2006-2017) [153]



[153] McCann Data; APQ.

APPENDIX F: PERCENTAGE OF NATIONAL AGGREGATE PRODUCTION QUOTA THAT IS EXCESSIVE PER MCCANN'S METHODOLOGY

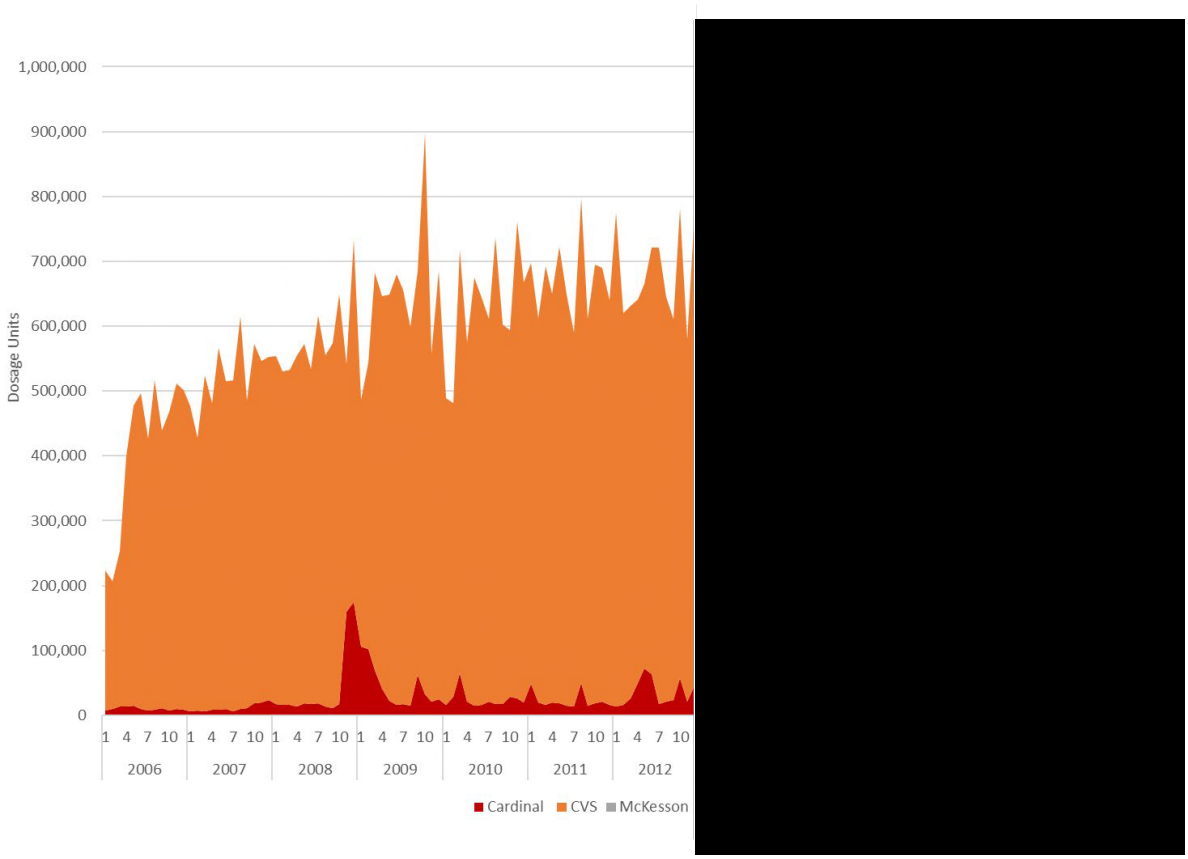
Table 24: Percentage of National Aggregate Production Quota that is Excessive per McCann's "Excessive Shipments" Methodology[154]

		Ohio Opioid Distributions		National Aggregate Production Quota without Buffer	
Year	Interpolated Baseline	MME per Capita	Percent that is Excessive per McCann's Methodology	MME per Capita	Percent that is Excessive per McCann's Methodology
1997	125.69	125.69		0.00	
1998	132.62	147.36	10.1%	340.57	61.1%
1999	140.42	182.90	23.4%	408.98	65.7%
2000	148.23	259.18	42.8%	528.74	72.0%
2001	156.89	299.05	47.7%	648.43	75.8%
2002	165.56	355.39	53.4%	700.46	76.4%
2003	175.10	443.81	60.7%	819.85	78.6%
2004	184.63	540.89	65.9%	1128.94	83.6%
2005	195.03	560.83	65.3%	1176.91	83.4%
2006	205.43	642.31	68.0%	1218.04	83.1%
2007	216.70	698.65	68.9%	1339.26	83.8%
2008	228.84	768.00	70.2%	1387.66	83.5%
2009	241.84	818.27	70.5%	1533.55	84.2%
2010	254.84	856.41	70.2%	1612.02	84.2%
2011	269.58	867.68	69.0%	1590.39	83.0%
2012	283.45	796.60	64.4%	1823.91	84.5%
2013	[redacted]			2032.82	85.2%
2014				2026.95	84.4%
2015				2049.06	83.7%
2016				1981.02	82.2%
2017				1585.67	76.5%
2018				1372.34	71.3%
Total (1997-2017)				**25,933.23**	**82.0%**

[154] McCann Report, Table 44; APQ.

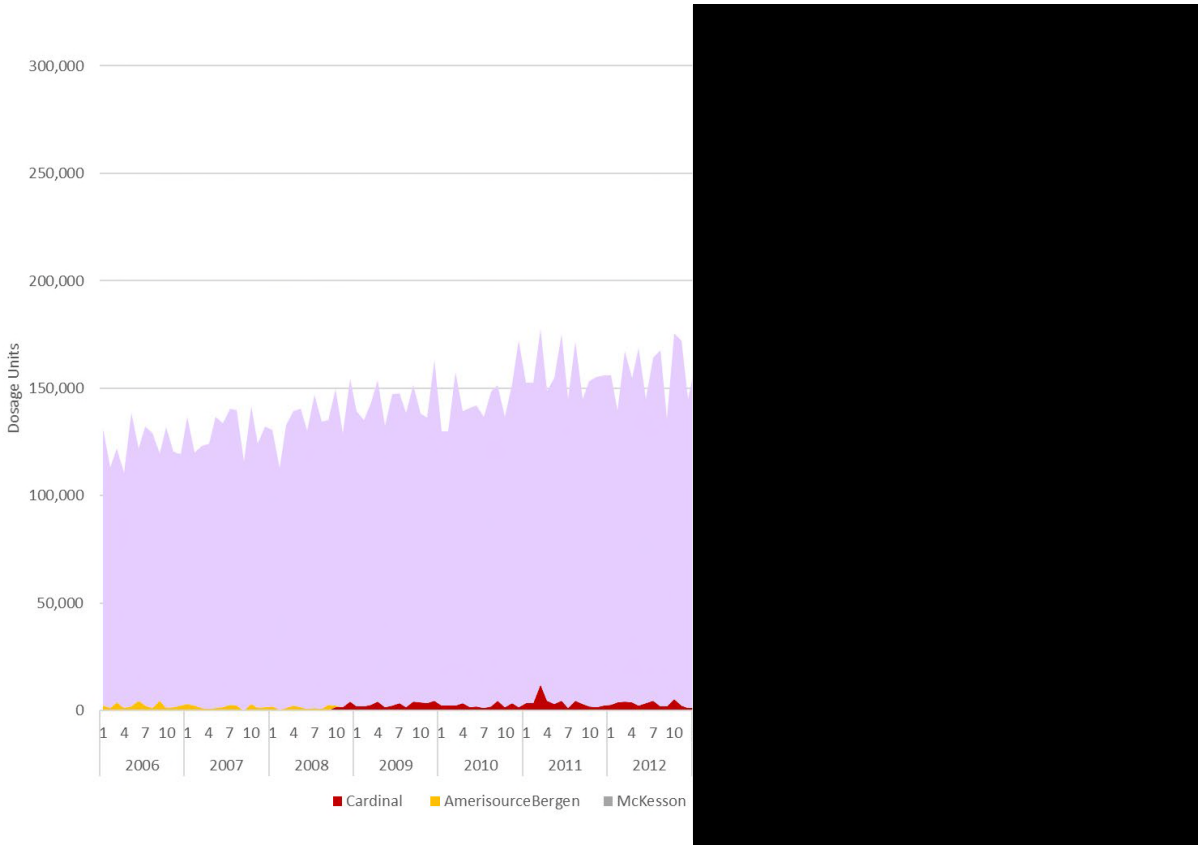
APPENDIX G: DISTRIBUTIONS TO CVS, DISCOUNT DRUG MART, AND WALGREENS PHARMACIES

Figure 11: Hydrocodone Shipments to CVS Pharmacies by Distributor (2006-2017)[155]



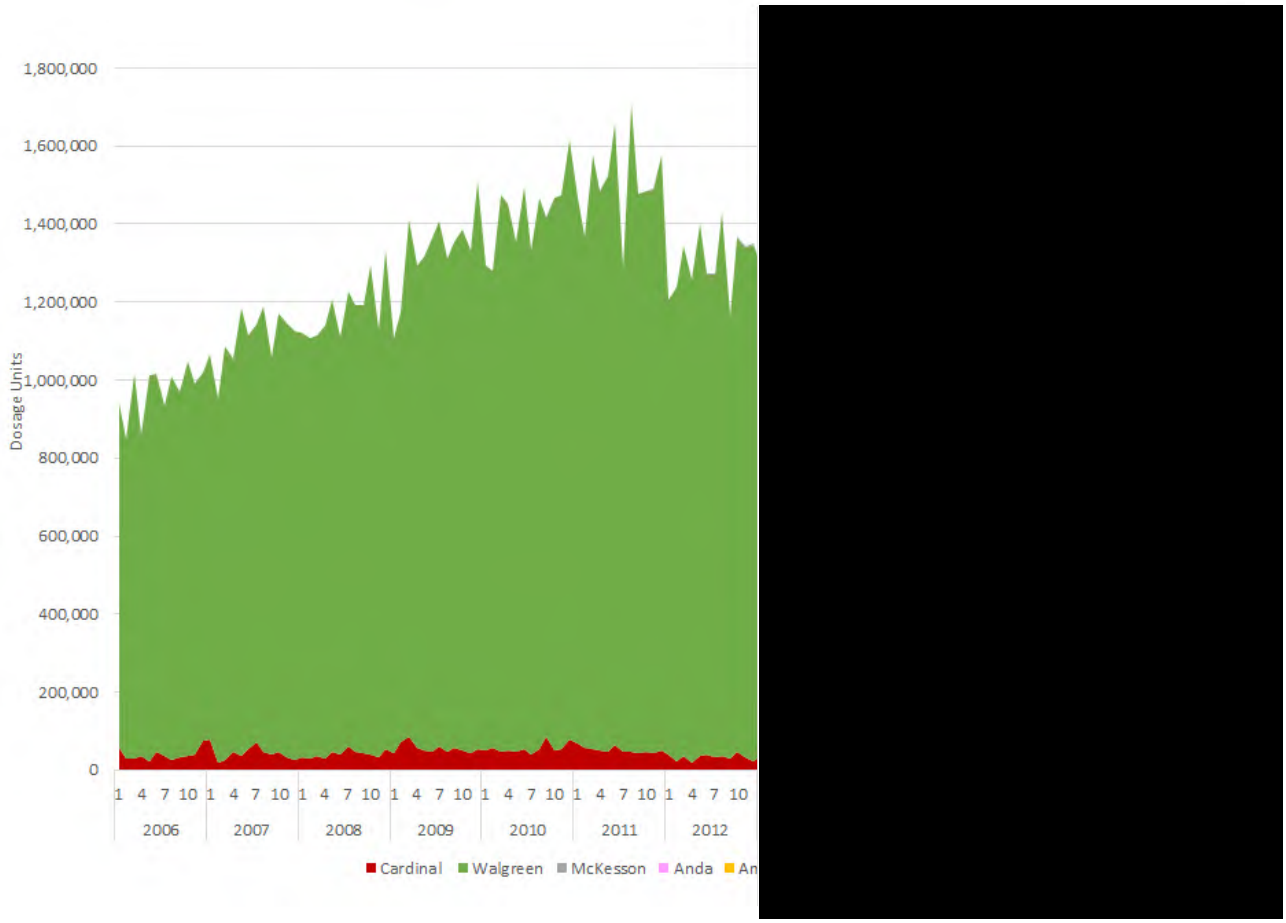
[155] McCann Dataset.

Figure 12: Hydrocodone Shipments to Discount Drug Mart Pharmacies by Distributor (2006-2017)[156]



[156] McCann Dataset.

Figure 13: Opioid Shipments to Walgreens Pharmacies by Distributor (2006-2017)[157]



[157] McCann Dataset.

APPENDIX H: CARDINAL DISTRIBUTIONS TO CVS STORES

143. I have analyzed the percentage of Track 1 CVS distributions which are shipped by Cardinal in Table 26. In aggregate, Cardinal ships [redacted] of all CVS pharmacies' dosage units.

Table 25: Cardinal and CVS Chain Warehouse Distributions to CVS Stores (2006-2014)[158]

	Opioid & Non-Opioid Volume		
Year	Total Dosage Units	% Cardinal	% CVS
2006	263,623,529	14.7%	85.3%
2007	269,629,209	14.6%	85.4%
2008	270,747,188	15.5%	84.5%
2009	304,024,310	15.8%	84.2%
2010	309,476,773	14.7%	85.3%
2011	321,689,126	15.3%	84.7%
2012	347,845,770	16.9%	83.1%
2013	[redacted]		
2014			
Total			

[158] McCann Dataset; Cardinal Opioid Distribution Data; Cardinal Non-Opioid Distribution Data; CVS Distribution Data.

ATTACHMENT 1

Curriculum Vitae

JOHN J. (TRI) MACDONALD, III
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SUMMARY

Tri MacDonald is a senior leader in Berkeley Research Group's Health Analytics Practice in Washington, DC. Mr. MacDonald has nearly thirty years of experience providing economic, financial, accounting and data management consulting services to clients in the healthcare, financial services, technology, and government contracting industries. These services have been primarily related to commercial litigation and other types of disputes. For more than fifteen years, he has focused primarily on healthcare and other claim intensive engagements involving intensive data management and analysis, fraud investigations, regulatory and contract compliance, cost allocations, records reconstruction, review of billing procedures and quantification of economic damages.

Mr. MacDonald consults with clients on a wide variety of economic, financial, accounting and systems related issues. These include lost profit determination, cost accounting issues, asset valuation, systems conversions, fraud and other special investigations, and large-scale data management. These issues have arisen on engagements involving breach of contract, product liability, fraudulent claims processing, breaches of fiduciary duties, negligence, misappropriations of funds, violations of the False Claims Act, professional malpractice, and others. Mr. MacDonald has extensive experience advising clients and counsel on such issues as cash flow projections, discounting, fixed versus variable cost determination, data verification and integrity, complex statistical analyses, and others.

Mr. MacDonald has worked extensively with issues related to pricing and risk sharing provisions contained in contracts between payers, providers and manufacturers in the healthcare arena. He has been engaged to advise on contracting strategies, the development and execution of performance metrics and the assessment of compliance with contractual obligations. Among other things, he has addressed the financial justification for various types of risk and price protection terms in contracts and assessed whether said terms were adequately satisfied. For example, Mr. MacDonald has provided testimony related to the rationale behind "most-favored-nations" pricing terms in PBM managed care contracts and the extent to which these terms were appropriately met.

Mr. MacDonald has substantial experience in matters involving large volume claim processing and loan processing facilities. These engagements have included regulatory compliance reviews, statistical trend analyses, data reconstruction, fraud and other special investigations, collateral monitoring and analysis, intensive data conversion and data merging issues, due diligence reviews and loan/claim curing procedures. Mr. MacDonald's work on these matters has been undertaken for a variety of clients including pharmaceutical companies, PBMs, mail order pharmacies, insurance companies, hospitals, international banks, Fortune 500 companies, parties to securitized debt deals, third party processors, and others.

Mr. MacDonald has extensive experience dealing with a wide range of parties, including hospitals, clinical laboratories, major pharmaceutical companies, pharmacy benefit managers, Blue Cross/Blue Shield plans, commercial insurers, pharmacies, nursing homes, Medicaid and Medicare programs, employee health plans and third party administrators.

PROFESSIONAL EXPERIENCE

Litigation Support

- On many occasions, Mr. MacDonald has been tasked with leading large, multi-disciplined consulting teams dealing with complex litigation involving multiple plaintiffs and / or defendants. Several of these matters have involved assisting joint defense groups to address complicated discovery and damages issues related to massive class action lawsuits brought by coordinated groups within the plaintiffs bar. He is experienced in dealing with issues related to government regulations, market conduct, economic performance, and advanced statistical analyses.

- Mr. MacDonald helped lead a team that provided healthcare billing and payment expertise, as well as electronic healthcare data discovery assistance, to a number of managed care entities who were defending themselves in class action litigation brought by physicians who claimed that the managed care entities routinely and unfairly denied, delayed, and diminished payment for services rendered to their members. Mr. MacDonald provided consultative support and analysis to the managed care entities' outside legal counsel on numerous issues, including financial exposure modeling, tutorials regarding physician coding and billing, tutorials regarding the managed care payment process, extraction, consolidation and analysis of electronic billing and payment data, coordination of hard copy medical record discovery, organization and expert analysis, deposition preparation assistance, and other analyses.

- On a large product liability engagement, Mr. MacDonald led a team tasked with analyzing a database of over 500 million healthcare claims. This work involved detailed trend analysis on attributes such as utilization, disease mix, demographic characteristics and eligibility status. This engagement also involved an extensive review of the data to identify

potential DRG up-coding, unbundling, regulatory claim processing violations, duplicate claim payments, and other issues related to data and processing integrity.

- Mr. MacDonald assisted counsel for a large Pharmacy Benefit Manager (PBM) in a breach of contract lawsuit alleging overpricing of drugs in mail and retail channels, breach of "most-favored-nations" pricing provisions, inappropriate rebate withholding, and improper drug switching. Mr. MacDonald developed analyses that required an in-depth understanding of the PBM's contractual relationships with its clients and pharmaceutical manufacturers, as well as its mail service pharmacy operations, retail pharmacy claim management offerings, and claims processing systems. He provided testimony in state court.

- Mr. MacDonald also assisted a PBM in a large *qui tam* action brought on behalf of the Federal government. Mr. MacDonald coordinated the acquisition of over two terabytes of highly relational mainframe data and managed the efficient analysis of that data. Ultimately, he performed numerous complex analyses regarding the PBM's alleged failure to meet various performance standards and offer savings through its drug interchange program, submitted several expert reports in the case and provided deposition testimony.

Fraud / Regulatory Compliance Investigations

- Specifically related to fraud and other special investigations, Mr. MacDonald has headed up several teams working on behalf of clients to identify the nature, cause and magnitude of the occurrence of fraud. These matters have involved allegations of fraudulent processing and billing ranging from a few million dollars to several billion dollars. His work has involved identifying specific instances of fraud, if any, determining the circumstances which allowed the fraud, if any, to occur, and assisting in the creation and implementation of procedures to minimize the likelihood of future fraud. A primary focus of this work has been to isolate claims and/or other transactions that have been affected by alleged fraud from untainted transactions to minimize the impact of damaging allegations on the clients' ongoing business operations.

- Mr. MacDonald has led several engagement teams tasked with performing statistical attribute sampling on healthcare billing and claims systems. These sampling processes have been designed and executed to make statistically valid estimates of certain characteristics of the entire billing or claims transaction populations. The characteristics reviewed have included compliance with regulatory rules and regulations, utilization trends, adherence to established medical best practices, and potential occurrences of fraud.

- Mr. MacDonald has worked with a national pharmaceutical company in response to allegations that the company inappropriately billed for certain products and services. In his role as Project Director, he oversaw the review of historical billing practices and patterns by product type. This project involved the restoration, validation and analysis of large amounts of archived billing data, as well as the review of historical accounting and financial data.

- Mr. MacDonald has worked with a large mail order pharmacy in response to allegations that the company inappropriately applied payments to specific patient accounts and failed to properly process refunds in instances involving duplicative or excess payments. His work on this matter involved reconstructing historical data records, comparing the electronic data to archived payment remittances and establishing the extent to which payments were inappropriately applied to patient accounts.

EDUCATION

B.S.B.A. - Accounting, Georgetown University, 1986

PRESENT POSITION

President, Berkeley Research Group, 2010 - present

PREVIOUS POSITIONS

Sr. Managing Director / Healthcare Practice Chair, LECG, LLC, 2006-2010

Managing Director / Healthcare Practice Chair, Navigant Consulting, Inc., 1986-2006

TESTIMONY EXPERIENCE

Trial / Arbitration Testimony

- *IMS Health Incorporated v. Medco Health Solutions, Inc.* in the American Arbitration Association, No. 14 194 Y 00001 08
- *Horizon Blue Cross Blue Shield of New Jersey v. Medco Health Solutions Inc., et al.* Superior Court of New Jersey for the Law Division of Bergen County, Docket No. L-9581-04
- *Board of the State Teachers Retirement System of Ohio v. Medco Health Solutions, Inc, et al.* – Court of Common Pleas, Hamilton County, Ohio, Civil Action No. A0309929

Deposition Testimony (Last 10 Years)

- *DaVita Healthcare Partners, Inc., et al. v. The United States* in the United States Court of Federal Claims, Case No, 11-297C
- *United States of America ex rel. Susan Ruscher, State of California ex rel. Susan Ruscher, et al. vs. Omnicare, Inc., et al.* in the United States District Court of Southern District of Texas, Houston Division, Civil Case No. 08-3396
- *Shenzhen Mindray Bio-Medical Electronics Co., LTD. v. Beckman Coulter, Inc.* in the Hong Kong International Arbitration Centre, Case No. A12112

- *Amerigroup Texas, Inc. v. Cook Children's Healthcare System, et al* in the District Court of Tarrant County, Texas, Docket No. 153-232258-08

- *IMS Health Incorporated v. Medco Health Solutions, Inc.* in the American Arbitration Association, No. 14 194 Y 00001 08

- *Group Hospitalization and Medical Services (d/b/a Carefirst Blue Cross Blue Shield) v. Merck-Medco Managed Care, L.L.C., et al.* Superior Court of New Jersey for the Law Division of Camden County, Docket No. L-4144-03

- *Horizon Blue Cross Blue Shield of New Jersey v. Medco Health Solutions Inc., et al.* Superior Court of New Jersey for the Law Division of Bergen County, Docket No. L-9581-04

- *United States of America, et al., v. Merck-Medco Managed Care, L.L.C., et al.* – United States District Court for the Eastern District of Pennsylvania, Case No. 00-cv-737

- *Board of the State Teachers Retirement System of Ohio v. Medco Health Solutions, Inc, et al.* – Court of Common Pleas, Hamilton County, Ohio, Civil Action No. A0309929

- *United States ex rel. Michael D. Watson v. Connecticut General Life Insurance Company* - United States District Court for the Eastern District of Pennsylvania

ATTACHMENT 2

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Cardinal Health - Retail Pharmacy Self Questionnaire (New Choice Pharmacy), 03_CAH_MDL2804_00000609_CAH_MDL_2804_002	CAH_MDL_2804	00000609	00000613
Cardinal Health DEA Compliance Manual, January 1999	CAH_MDL_PRIORPROD_DEA07	01383895	01384238
Chemical Handler's Manual, January 2004	CAH_MDL_PRIORPROD_DEA07	01198690	01198758
Drug Enforcement Administration, Diversion Investigators Manual (1990)	CAH_MDL_PRIORPROD_DEA07	01176247-R	01176558-R
Cardinal Accrual Data	CAH_MDL2804	03240088	
Cardinal Allocation Date Data	CAH_MDL2804	03263594	
Cardinal Data - Suspicious Orders	CAH_MDL2804	00000013	
Cardinal Health Due Diligence Memo (New Choice Pharmacy), 01_CAH_MDL2804_00000605_CAH_MDL_2804_002	CAH_MDL2804	00000605	00000618
Cardinal Held Orders	CAH_MDL2804	0135242	
Cardinal Internal ADC Monitoring Data	CAH_MDL2804	00619125	
Cardinal Non-Opioid Aggregated Data (1996-2005; 2018)	CAH_MDL2804	00617996	
Cardinal Non-Opioid Line Distribution Data (2006-2012)	CAH_MDL2804	00617997	
Cardinal Non-Opioid Line Distribution Data (2013-2017)	CAH_MDL2804	00059301	
Cardinal Non-Opioid NDC Look-Up Table	CAH_MDL2804	00618000	
Cardinal Opioid Distribution Data Reproduction (1996-2018)	CAH_MDL2804	03263593	
Cardinal Threshold Changes Data	CAH_MDL2804	00619126	
Drug Enforcement Administration, Diversion Investigators Manual (1996)	CAH_MDL2804	02203353	02203357
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000003782 (1)	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124147	
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CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124149	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124150	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124151	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124152	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124153	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124154	
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CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124156	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124157	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124158	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124159	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124160	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124161	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124162	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124163	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124164	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124165	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124166	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124167	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124168	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124169	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124170	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124171	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124172	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124173	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124174	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124175	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124176	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124177	
CVS Non-Opioid and Hydrocodone Distribution Data	CVS-MDLT1	000124178	
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2018-09-26 Cameron, Todd (Montana AG) (condensed with index)			
2018-11-06 Deposition of Cameron, Errata			
2018-11-30 Deposition of Reardon, Steve (condensed)			
2019-01-23 Deposition of Griffin, Eric			
2019-02-28 Deposition of Wright, Kyle (full)			
2019-03-15 Deposition and Exhibits of Ashley, Demetra (condensed)			
2019-04-11 Deposition and Exhibits of Harper-Avilla, Stacy (full)			
2019-04-17 Deposition of Prevoznik, Thomas (condensed)			
2019-04-25 Deposition of Egilman, David (full with index)			
2019-04-25 Deposition of Gruber, Jonathan (full with index)			
2019-04-25 Deposition of Howard, June (condensed)			
2019-04-25 Deposition of Howard, June			
2019-04-26 Deposition of Egilman, David (full with index)			
2019-04-26 Deposition and Exhibits of Rannazzisi, Joseph (condensed)			
2019-04-26 Deposition of Cutler, David (with full index)			
2019-04-27 Deposition of Cutler, David (with full index)			
2019-04-29 Deposition of Keyes, Katherine (full with index)			
2019-04-30 Deposition of McGuire, Thomas (full with index)			
21 C.F.R. § 1301.13(e)			
21 C.F.R. § 1301.72			
21 C.F.R. § 1301.74			
21 C.F.R. § 1301.74(b)			
21 C.F.R. § 1301.75			
21 C.F.R. § 1301.75(b)			
21 C.F.R. § 1304.11(e)(3)			
21 C.F.R. § 1304.11(e)(6)(ii)			
21 C.F.R. § 1306.04(a)			
21 C.F.R. § 1306.05			
21 C.F.R. § 1306.05(a)			
21 C.F.R. § 1306.06			
21 C.F.R. § 1306.11(b)			
21 U.S.C. § 801			
21 U.S.C. § 811(b)			
21 U.S.C. § 812(b).			
21 U.S.C. § 823(b)			
21 U.S.C. § 824			
21 U.S.C. § 826			
21 U.S.C. § 826 (a)(1)			
21 U.S.C. § 826 (b)			
21 U.S.C. § 829(a)			
21 U.S.C. § 829(b)			
21 U.S.C. § 842			
28 C.F.R. § 0.100			

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Consensus Document, Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances. Available at https://nabp.pharmacy/wp-content/uploads/2016/07/Red-Flags-Controlled-Substances-03-2015.pdf, last accessed 5/8/2019.			
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Drug Enforcement Administration, Policy Statement, 71 Fed. Reg. 52715, 52723 (September 6, 2006).			
Drug Enforcement Administration, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, Establishment of total annual needs, 21 U.S.C. § 826(a). Available at https://www.deadiversion.usdoj.gov/21cfr/21usc/826.htm, last accessed 5/8/2019.			
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Expert Report of Craig J. McCann, Ph.D., CFA, (March 25, 2019)			
Expert Report of Dr. Seth Whitelaw, Examination of Compliance Standards for Opioid Manufacturers and Distributors, (April 15, 2019)			
Expert Report of James E. Rafalski, Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances (April 15, 2019)			
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FDA Recommends Reclassifying Hydrocodone to Schedule II, Available at https://www.pharmacytoday.org/article/S1042-0991(15)31070-7/pdf, last accessed 5/10/2019.			
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In Re National Prescription Opiate Litigation, The County of Summit, Ohio, et al., v. Purdue Pharma L.P., et al., Case No. 17-md-2804, Amended Complaint and Jury Demand, (April 25, 2018), ("Summit Complaint")			
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Cardinal Health, Inc.'s Objections and Responses to Plaintiffs' First Set of Requests for Production of Documents (May 29, 2018)			
Cardinal Health, Inc.'s Objections and Supplemental Responses to Plaintiffs' First Set of Interrogatories (November 30, 2018)			
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Cardinal Health, Inc.'s Revised Objections and Third Supplemental Responses to Plaintiffs' First Set of Interrogatories (March 25, 2019)			
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